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AMENDED LIBEL.

Filed Oct. 2, 1945. Harry F. Rabe, Clerk.

UNITED STATES DISTRICT COURT, SOUTHERN DISTRICT OF OHIO, WESTERN DIVISION.

No. 1314 Civil.

FDC No. 17606.

UNITED STATES OF AMERICA

versus

16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC" AND A NUMBER OF LEAFLETS ENTITLED "THE ROAD TO HEALTH".

The libel of the United States of America, by Byron B. Harlan, United States Attorney, who in this case prosecutes in its behalf, and respectfully represents as follows:

I.

This libel is filed by the United States of America in its own right, and prays seizure for condemnation of a certain article of device, to-wit: 13 articles of device, more or less, intended for the diagnosis and treatment of disease labeled "Sinuothermic". Two of these devices, bearing numbers "X8" and "X10", are of the so-called "Master Unit" type; the others, bearing numbers "T20", "T22", "T23", "T25", "T26", "T28", "T29", "T32", "T33", "T34", "T60", "T50", "T51", and "T76", are of the so-called "Treating Unit" type.

Also, a number of leaflets entitled "The Road to Health" which accompany the article of device.

II.

Your libelant represents to the Court that the aforesaid 16 articles, of device, more or less, labeled "Sinuothermic" and a number of leaflets entitled "The Road to Health" are now in the City of Cincinnati, County of Hamilton, State of Ohio, in the Western Division of the Southern Judicial District of Ohio, and within the jurisdiction of this Court, in the possession of J. J. H. Kelsch, D. C.

III.

Your libelant further represents that said 16 articles of device, more or less, labeled "Sinuothermic" and the said leaflets have been transported in interstate commerce via Railway Express Agency and U. S. Mail respectively, on or about July 25, August 14, September 21, 1945, and early in July, 1945, respectively, by Fred Urbeteit, from Tampa, in the State of Florida, to and into Cincinnati, in the State of Ohio; that said 16 articles of device, more or less, labeled "Sinuothermic" and the said leaflets have been so as aforesaid transported in interstate commerce and are now in the possession of J. J. H. Kelsch, D. C., Cincinnati, Ohio, as aforesaid, and that said 16 articles of device, more or less, labeled "Sinuothermic" and the said leaflets remain unsold and in the original boxes wherein the same were transported.

IV.

Your libelant represents that said article of device contained in the boxes as hereinabove set forth is held with-

in the jurisdiction of this Honorable Court illegally and in violation of the Act of Congress approved June 25, 1938, known as the Food, Drug and Cosmetic Act, and is liable to seizure and condemnation as provided in said Act, for the reason that said article of device and said leaflets are misbranded within the meaning of said Act of Congress, particularly Section 352(a), Title 21, United States Code, in that the statements and references relative to the curative and therapeutic claims of value for said articles in the diagnosis, cure, mitigation, treatment and prevention of diseases of man which appear in the labeling of said devices, namely, the leaflet entitled "The Road to Health", which said leaflet and a number of copies thereof accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce, are false and misleading in this, that such statements and references represent and suggest that the said article of device is effective in the treatment of abscesses of the liver, painful breathing, internal growths, arthritis, hardening of the arteries, heart disease, paralysis, cancer, diabetes, tuberculosis, prostate trouble, deficient hearing, hay fever, infantile paralysis, glandular and nervous disorders, tumor, asthma, diseased kidneys, nervousness, nerve disorders, low blood pressure, ulcerated colon, appendicitis, obstructed colon and menstrual dysfunction or discomfort associated with menstruation, whereas, the articles are not effective for such purposes.

Wherefore, In Consideration Of The Premises, Your Libelant Prays:

First: That said article of device and said leaflets, as hereinabove described, may be processed against and seized for condemnation in accordance with said Act of Congress, particularly Section 334, Title 21, United States

Code, and that to this end this Honorable Court may order to issue process of attachment in due form of law, according to the course of this Court in cases of admiralty and maritime jurisdiction, so far as is applicable to this case, and that said J. J. H. Kelsch, D. C., and all other persons having or pretending to have any right, title or claim in or to said article of device may be cited to appear herein and answer all and singular the premises aforesaid.

Second: That by an appropriate order this Honorable Court may adjudge and decree that said article of device contained within the boxes aforesaid and said leaflets shall be condemned at the suit of the libelant, according to the provisions of the Act of Congress aforesaid.

Third: That this Honorable Court may make all such further orders, decrees and judgments as may be necessary in the premises and may grant your libelant a decree for the cost of this proceeding against the claimants, owners or holders of the article of device and said leaflets so condemned, and that your libelant may have such other and further relief as the nature of the case may require.

(Sgd.) BYRON B. HARLEN,
United States Attorney.
S. D. O.

On the 29th day of October, 1945, Claim of Fred Urbeteit was filed in the following words, to-wit:

4 ANSWER TO AMENDED LIBEL CLAIM OF FRED URBETEIT.

Claimant, Fred Urbeteit, a citizen and resident of the City of Tampa, County of Hillsborough and State of Florida, residing in the Southern District of Florida, by his Attorneys, H. O. Pemberton of Tallahassee, Florida, and Rudolf Licht of Cincinnati, Ohio, makes his claim to certain of the property described in the Amended Libel, and for answer to the matters and things therein alleged, says:

I.

The six Sinuothermic Machines or devices described in the Amended Libel as bearing numbers "X8", "X10", "T20", "T25", "T26" and "T32", were sold by Claimant to J. J. H. Kelsch, D. C., of Cincinnati, Ohio, named in the Amended Libel as being in possession thereof, and Claimant has no property interest therein. The other ten Sinuothermic Machines described in the Amended Libel are the property of Claimant and were placed in the possession of J. J. H. Kelsch of Cincinnati, Ohio, under a rental agreement providing for the payment of rent to Claimant for the privilege of using the said Sinuothermic Machines.

The leaflets described in the Amended Libel as being entitled "The Road to Health", were published several years ago as an advertisement of the school and clinic operated by Sinuothermic Institute, Inc., of Tampa, Florida, and of which Claimant is the President, and were given to J. J. H. Kelsch, at his request, to be used by

him in connection with his own advertising, and Claimant does not claim any property interest therein.

II.

Claimant admits the allegations of Paragraph II of the Amended Libel.

III.

Claimant admits the allegations of Paragraph III of the Amended Libel except that the dates of shipment therein alleged may not be accurate and Claimant has no knowledge as to the Sinouthermic Machines remaining in the original boxes wherein they were transported but believes such allegation to be untrue as to all machines other than those received by J. J. H. Kelsch after the original Libel was filed. Claimant further says that the Sinuothermic Machines were delivered to a transfer company in Tampa, Florida for crating and shipping on July 18, 1945, August 18, 1945 and September 19, 1945, the shipments being made by express, and that the leaflets were shipped from Tampa, Florida, on September 1, 1945, by Parcel Post.

IV.

Claimant denies the allegations contained in Paragraph IV of the Amended Libel and avers that the leaflets netitled "The Road to Health" do not constitute a labeling of the Sinuothermic Machines and did not accompany the same within the meaning of the Act of Congress referred to; and Claimant denies that the said leaflets are false and misleading.

Further answering the allegations of Paragraph IV of the Amended Libel, Claimant alleges that no official or employee of the United States has any actual knowledge as to the effectiveness of the Sinuothermic Machine in the diagnosis and treatment of the diseases of man and that no practitioner of any of the healing arts, other than a limited number who have received some instruction from claimant, have any actual knowledge as to the effectiveness of the machine or knowledge of how it is properly used, although there are many people who had been treated by Claimant with the Sinuothermic Machine and know of its effectivness in their respective cases. For this reason and in order that there may be had in this case such an adequate judicial determination and complete judicial finding of facts pertinent to the issues in this cause that the officials of the Federal Security Agency will be fully aware of the nature, merit and effectiveness of the Sinouthermic Machine and method of diagnosis and treatment of the diseases of man, claimant makes the following offer:

In co-operation with such representatives of the United States and such practioners of Medicine, Osteopathy, Chiropractic and Naturopathy or any of them and such other persons as may be approved by the Court, Claimant will ocnduct a series of tests on as many persons and over such period of time as may be designated by the Court, the persons to submit to the tests being wherever possible persons who have been examined and treated by practitioners of the Medical Profession but who still suffer from the disease or ailment they had before such treatment, and all persons who submit to the tests to be examined by the physicians designated by the Court before examination and treatment by Claimant. At the end of the period designated by the Court the persons designated and approved by the Court to work with

Claimant in making the tests shall report their findings to the Court, the same to be received as evidence in this cause.

(Sgd.) H. O. PEMBERTON,
(H. O. Pemberton)
(Sgd.) RUDOLF LICHT.
(Rudolf Licht)

State of Florida,
County of Hillsborough.

Before me, the undersigned authority, personally appeared Fred Urbeteit, who being first duly sworn says that he is the claimant named in the foregoing claim and answer, that he has read the same and that the statements therein contained are true.

(Sgd.) FRED URBETEIT.
(Fred Urbeteit)

Sworn to and subscribed before me this 22nd day of October, 1945.

(Sgd.) GENE S. ELLIOTT,
(Seal) (Gene S. Elliott)
Notary Public, State of Florida at Large.

My commission expires October 19, 1948. Bonded by Mass. Bonding & Ins. Co.

On the 23d day of September, 1946, A Certified Copy of the Order Transferring Libel to the Northern District of Florida, was filed in the following words, to-wit:

7 ORDER TRANSFERRING LIBEL TO THE NORTHERN DISTRICT OF FLORIDA.

The Libelant United States of America, and the claimants Fred Urbeteit and J. J. H. Kelsch having hereto-

fore stipulated and agreed that the above styled Libel for Condemnation proceedings be removed for trial to the Northern District of Florida at Gainesville, Florida, and all parties having consented thereto, the Court finds that said stipulation should be granted, and that this action should be removed to the United States District Court for the Northern District of Florida at Gainesville, Florida.

It is therefore ordered, adjudged and decreed by the Court that this action be, and the same is hereby transferred for further proceedings and trial to the United States District Court for the Northern District of Florida at Gainesville, Florida, and the Clerk of this Court is hereby ordered and directed to transfer all papers and records filed herein to the United States District Court for the Northern District of Florida at Gainesville, Florida.

(Signed) JOHN H. DRUFFEL,
J.

(Seal)

Have seen.

(Sgd.) RAY J. O'DONNELL,
United States District Attorney.

(Sgd.) WILLIAM J. DAMMARELL,
Assistant United States Dist. Atty.

(Sgd.) H. O. PEMBERTON & RUDOLF LICHT,
Attorneys for Claimants.

A True Copy of the Original. Filed Sep. 20, 1946. Attest: Harry F. Rabe, Clerk. By Harry F. Rabe, Clerk. Certified Sep. 20, 1946.

On the 10th day of December, 1946, Consent to Amendment and Claim of Fred Urbeteit and J. J. H. Kelsch was filed in the following words, to-wit:

CONSENT TO AMENDMENT AND CLAIM OF FRED URBETEIT AND J. J. H. KELSCH.

Come now Fred Urbeteit of the City of Tampa, Hillsborough County, Florida, and J. J. H. Kelsch of the City of Cincinnati in Hamilton County, Ohio, Claimants in the above entitled cause, and consent to the filing by the United States of America of a second amended libel, a copy of which has heretofore been tendered to the Court for filing; and for answer to the said second amended libel and claim to the property therein described, say:

1. Claimants admit the recital of previous pleadings contained in paragraphs 1 to 5, both inclusive.

2. Claimants admit the shipment in interstate commerce of the devices and leaflets mentioned in paragraph (6) but deny that the devices and leaflets were shipped together or that they relate to each other, and neither admit nor deny the dates of the shipments alleged because of a present lack of exact knowledge as to the dates of shipment.

3. Claimants deny the allegations of paragraph (7).

4. Claimants admit the allegations of paragraph (8).

5. Claimants deny the allegations of paragraph (9).

6. Claimants re-new their statements of ownership of the libeled property set forth in their original claims without the necessity of repeating the same herein and

the statements of ownership and possession of the property contained in said original claims is by reference made a part hereof.

(Sgd.) H. O. PEMBERTON,
(H. O. Pemberton)
Attorney for Claimants.

On the 9th day of January, 1947, Second Amended Libel of Information was filed in the following words, to-wit:

8 SECOND AMENDED LIBEL OF INFORMATION.

To the Honorable Augustine V. Long, Judge of the United States District Court for the Northern District of Florida:

Now comes the United States of America, by George Earl Hoffman, United States Attorney for the Northern District of Florida, and shows to the Court:

(1) That a libel of information was filed in the Southern District of Ohio, Western Division, by the United States of America, on September 27, 1945, praying the seizure and condemnation of 13 articles of device, as hereinafter set forth, labeled, in part, "Sinuothermic", and being numbered "X8" and "X10" of the so-called "Master Unit" type; the others bearing numbers "T20", "T22", "T23", "T25", "T26", "T28", "T29", "T32", "T33", "T34", "T60, of the so-called "Treating Unit" type, including their accompanying labeling, to-wit, a number of leaflets relating thereto, entitled "The Road to Health", in accordance with the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 301 et seq.).

(2) That thereafter, to-wit, on October 2, 1945 an amended libel of information was filed in the Southern District of Ohio, Western Division, by the United States of America, praying the seizure and condemnation of three additional articles of device, as hereinafter set forth, labeled, in part, "Sinuothermic", and bearing numbers "T50", "T51", "T76" of the so-called "Treating Unit" type; including their accompanying labeling, to-wit, a number of leaflets relating thereto, entitled "The Road to Health", in accordance with the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 301, et seq.).

(3) That thereafter one Fred Urbeteit of Tampa, Florida, intervened as claimant and filed answer on behalf of ten of the articles of device labeled in part "Sinuothermic" and bearing the numbers "T22", "T23", "T28", "T29", "T33", "T34", "T60", "T50", and "T51", "T76" of the so-called "Treating Unit" type; and J. J. H. Kelsch, D. C. of Cincinnati, Ohio, intervened as claimant and filed answer on behalf of six of the articles of device, labeled in part "Sinuothermic" and being numbered "X8" and "X10" of the so-called "Master Unit" type which had been seized by the U. S. Marshal pursuant to said libels and "T20", "T25", "T26" and "T32" of the so-called "Treating Unit" type.

(4) That thereafter, to-wit, on September 20, 1946 the libelant, the United States of America, and the claimants, Fred Urbeteit and J. J. H. Kelsch, D. C. entered into a stipulation and agreement that the libel for condemnation proceedings be removed for trial to the Northern District of Florida at Gainesville, Florida; that by order entered on September 20, 1946 the United States District Court for the Southern District of Ohio, finding that said stipulation should be granted, ordered, adjudged and decreed that said libel be transferred for fu-

ture proceedings and trial to the United States District Court for the Northern District of Florida, at Gainesville, Florida.

(5) That pursuant to 21 U. S. C. 334(f)(2) and leave of Court the United States of America files this, its second amended libel of information, in the Northern District of Florida and prays condemnation of articles of device so seized as aforesaid, as hereinafter set forth.

(6) That said 16 articles of device, more or less, labeled in part "Sinuotherm c", including the leaflets entitled "The Road to Health", relating thereto, were introduced into interstate commerce at Tampa, Florida, for shipment in interstate commerce to Cincinnati, Ohio, on or about July 25, 1945, August 14, 1945, September 21, 1945, and at divers other times—the more exact dates of which are unknown—between June 1, 1945 and September 28, 1945, and were then so shipped in interstate commerce from Tampa, Florida, to Cincinnati, Ohio.

(7) That the aforesaid articles of devices within the meaning of 21 U. S. C. 321(h), and when introduced into and while in interstate commerce were misbranded within the meaning of 21 U. S. C. 352(a) in that the statements and references, relative to the curative and therapeutic claims of value for said articles of device in the diagnosis cure, mitigation, treatment and prevention of diseases of man, which appear in the labeling of said article of devices, namely, the leaflets entitled "The Road to Health", a copy of said leaflets, marked exhibit "A", being attached hereto and made a part hereof, and which said leaflets and a number of copies thereof accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce, are false and misleading in this, that such statements and references represent and suggest that the said articles are effective in the diagnosis,

cure, mitigation, treatment, and prevention of painful breathing, internal growths, arthritis, hardening of the arteries, heart disease, paralysis, cancer, (internal; of brain; external), diabetes, tuberculosis, prostate trouble, deficient hearing, hay fever, infantile paralysis, glandular and nervous disorders, tumors of the bladder and uterus, uterine hemorrhage, diseased kidneys, nervousness, nerve disorders, peritonitis, low blood pressure, ulcerated colon, appendicitis, obstructed colon and menstrual dysfunction or discomfort associated with menstruation, whereas, the articles are not effective for such purposes.

(8) That the aforesaid 16 articles of device, more or less, labeled, in part, "Sinuothermic," including the aforesaid leaflets entitled "The Road to Health" were in the possession of J. J. H. Kelsch, D. C. at the city of Cincinnati, County of Hamilton, State of Ohio, in the Western Division of the Southern Judicial District of Ohio at the time of the filing of the original libel.

(9) That by reason of the foregoing the articles of device are liable to seizure and condemnation pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 334).

Wherefore, libelant prays that process in due form of law according to the course of this Court in cases of admiralty jurisdiction issue against the aforesaid articles of device; that all persons having any interest therein be cited to appear within and answer the aforesaid premises; that this Court decree of condemnation of the aforesaid articles of device and grant libelant the costs of this proceeding against the claimant of the aforesaid articles of device; that the aforesaid articles of device be disposed of as this Court may direct pursuant to the provisions of

said Act; and that libelant have such other and further relief as the case may require.

Dated: Nov. 21, 1946.

UNITED STATES OF AMERICA,
By G. E. HOFFMAN,
United States Attorney.

On January 23rd and 24th, 1947, Trial of said Cause before Honorable Augustine V. Long, United States District Judge, without a Jury, was held at Gainesville, Florida and the following is the TRANSCRIPT OF TESTIMONY adduced by the respective parties at said Trial as reported by the Official Court Reporter, to-wit:

In the District Court of the United States, in and for the Northern District of Florida.

The United States of America,
vs. No. G-73 C.
16 Articles of Device, More or Less, Labeled in part "Sinuothermic" including a number of Leaflets relating thereto Entitled "The Road to Health".

Gainesville, Florida,
January 23, 1947.

Before: Long, J., without a Jury.

Appearances:

H. V. Knight, Assistant U. S. Attorney, Gainesville, Florida, and Wm. W. Goodrich, Esquire, Attorney for the Food and Drug Administration, Washington, D. C., for the Plaintiff; and

H. O. Pemberton, Esquire, Tallahassee, Florida, for the Defendant.

Mr. Knight:

We have with us, Wm. W. Goodrich, of the Office of General Counsel of the Food & Drug Administration, who

has received this morning designation as Special Assistant United States Attorney for the purpose of this trial and we ask permission to have Mr. Goodrich participate in the trial.

The Court:

He will have the right anyway, as United States Attorney, without that.

(Thereupon, Mr. Goodrich, on behalf of the United States, made an opening statement to the Court; followed by Mr. Pemberton, on behalf of the Defendant, who made an opening statement to the Court.)

(Thereupon, at the request of Mr. Goodrich, the witnesses were placed under the Rule, after being called and duly sworn. It was agreed between counsel, however, that Dr. Kelsch, one of the claimants, and Mr. Pierce, one of the United States investigators, be excused from the Rule. Mr. Pemberton, counsel for the defendant, announced that he had no witnesses present at this time except Dr. Urbuteit, himself.)

SIDNEY WEISSENBERG was called as a witness on behalf of the United States and testified as follows:

16 Direct Examination.

By Mr. Goodrich:

Q. State your name and address, please.

A. Sidney Weissenberg; 3602 Washington Avenue, Cincinnati, Ohio.

Q. What is your occupation?

A. I am a food and drug inspector with the United States Food and Drug Administration.

Q. What are the duties of your position as food and drug inspector?

A. As a food and drug inspector I investigate the manufacture, distribution and handling of foods, drugs, cosmetics and devices.

Q. In the course of your duties, did you at any time in late August, or early September, 1945, have occasion to visit the office of Dr. J. J. H. Kelsch?

A. Yes, sir.

Q. Will you tell the Court about your visit?

A. I visited the dealer, J. J. H. Kelsch, on August 22, 1945 for the first time in connection with these devices.

Q. Will you tell the Court where Dr. J. J. H. Kelsch is located?

A. He is located on Ashland Avenue, 2421 Ashland Avenue, Cincinnati, Ohio.

Q. What did you do at the time of your first visit?

A. At the time of that first visit I accompanied Inspector McKellogg and I examined the devices that he had on hand, known as "sinuothermic" devices.

Q. By "he", you mean Dr. Kelsch?

A. That is correct; and I took photographs of those devices, noted the labeling on the devices and learned of the shipments involved in this particular case.

Q. Did you return after your first visit?

A. Yes. On September 5, 1945 I returned to the office of Dr. Kelsch and again examined the devices; and at that time, the second time, I also examined a number of leaflets known as "The Read to Health". I also obtained at that time copies of the records covering the first series of shipments for these devices known as "sinuothermic".

Q. Did you at that time collect a sample of the sinuothermic device which is under question in this suit?

A. I obtained on Sptember 5th, as a follow-up of the visit on August 22nd, a sample which is known as a "Documentary sample" of the device, and that consisted

of obtaining the information concerning the shipments and noting the labeling. In addition, I obtained a sample of the leaflet known as "The Road to Health", one of a number that he had on hand at that time.

Q. Did you at that time obtain certain stickers on the shipping cartons, from the shipping cartons?

A: Yes; there were shipping cartons in which two of the devices were still packed and I obtained a copy, rather obtained from the shipping case a shipping label which had the address of the dealer, J. J. H. Kelsch, and the name and address of the shipper, as well as the shipping record of the Railway Express Agency, covering that particular shipment, and a tag which was attached to the bindings of the shipping case, indicating the address of the shipment involved.

Q. I show you two shipping tags and ask if you can identify them?

A. Yes, the first one is the address label,—

Mr. Goodrich:

Mark these for identification.

(Same are marked U. S. Exhibits 1 and 2.)

Q. I show you exhibits marked U. S. 1 and U. S. 2, now tell the Court what those are.

A. Exhibit 1 is a sticker which was on the carton showing the address of the shipper, Dr. Fred Urbuteit, 307 W. Euclid Avenue, Tampa, Florida, and the address of the dealer, Dr. J. J. H. Kelsch, at Cincinnati, Ohio. Government Exhibit 2 is a tag tied to the package and again showing the address of the shipper and the dealer.

Mr. Goodrich:

We offer these in evidence as Government's Exhibits Nos. 1 and 2, respectively.

Mr. Pemberton:
No objection.

(Same are so marked and filed.)

Q. I hand you a form letter entitled, "Dear Patients", signed, "Dr. Fred Urbuteit", and ask if you can identify that and tell the Court where it was obtained.

A. Yes; this was obtained from Dr. Kelsch on the first visit on August 22, 1945.

Mr. Goodrich:
I ask that this be marked for identification as Government's Exhibit 3.

Q. I show you a circular entitled, "The Road to Health". Can you identify that circular?

A. Yes; this is a circular which I obtained from Dr. Kelsch on September 5, 1945 and it bears, in addition to my own initials and the date, 9/5/45, the name and address of Dr. Kelsch.

Mr. Goodrich:
We offer this in evidence as Government's Exhibit No. 4.

Mr. Pemberton:
No objections.

(Same is so marked and filed in evidence.)

Q. Did you at the time examine the machines carefully?

A. Yes, I did; as to the external portions of the machines and the attachments to the machines.

Q. Were there any particular markings or identifying numbers on the machines there?

A. Yes; the machines were labeled with the following statement: "U. S. Patent Sinuothermic Trade Mark"; and then also embossed in the machines was the serial number, such as "X-8" or "X-10", which was on the large machines, the so-called "Master" machines; and the smaller machines, or treating, or minor models, bearing the serial number "T" and then another number, such as "T-22" or "T-23", and so forth.

Q. Where were the leaflets in Dr. Kelsch's office?

A. On September 5, 1945 there were leaflets on the desk and in the desk; two being on the desk and four being in the desk of Dr. Kelsch.

Q. Are those the leaflets, "The Road to Health"?

A. Yes, "The Road to Health" are the leaflets that I am talking about, and these leaflets were upon the desk in the main consulting room of Dr. Kelsch within the reach and view of the patients who might consult him there.

Q. Where were the devices?

A. The devices, the master models of the devices were in the consulting rooms just off the main consulting room. There were two other rooms off the main consulting room, and one of each of the master models were in those rooms; and in addition, on August 22, there were two devices still wrapped in one of those off consulting rooms; and then in the treating rooms which Dr. Kelsch has in his establishment there were nine other treating models on August 22nd, and on September 5, 1945 the same situation existed except that one of the devices, No. T-60, was not there, it having been rented, according to the records obtained, rented to the Hoefker family.

Q. Did you take photographs of the devices?

A. Yes, I did take photographs of those devices.

Q. Are these the photographs (indicating)?

A. Yes, these are the photographs.

Mr. Goodrich:

We offer these photographs in evidence as Government's Exhibits Nos. 5 and 6.

Mr. Pemberton:

No objection.

(Same are so marked and filed in evidence.)

Q. Did you visit Dr. Kelsch again later in September?

A. Yes, on September 28th.

Q. And will you tell the Court about that viist?

A. On September 28th I accompanied Deputy U. S. Marshal, Raymond J. Griffin, to assist him in the seizure of those devices.

Q. And at that time did you encounter other machines not involved in the original seizure?

A. Yes, three additional treating model machines, minor model machines, also on hand at that time of a later shipment. Those machines bearing Serial numbers "T-50", "T-51", and "T-76".

Q. Did you collect a documentary sample of those devices?

A. Yes, I obtained a documentary sample again of the same type of sample obtained before, which was an examination of the devices, the labeling of the devices, and obtained the records covering the particular shipment.

Q. And were those machines later included in the seizure?

A. Yes; on October 2, 1945, as a result of the amended libel, I again accompanied Deputy U. S. Marshal Raymond J. Griffin to assist in the seizure of the three devices of the numbers I have already mentioned.

Mr. Goodrich:
You may inquire.

Cross Examination.

By Mr. Pemberton:
Q. When were these machines received by Dr. Kelsch that you have testified to?
A. I would have to have some more records.

Mr. Goodrich:
If your Honor please, we have the Railway Express Agent here who has those exact records.

Q. There is just one question I would like to ask you. I know that it is habitual, probably, in your life of work, but why do you use the word "dealer" with reference to a doctor using these machines in his practice?
A. The word "dealer" as applied by us indicates the person or firm who receives the devices on hand and then either distributes them or employs them by himself.
Q. You are using it just as a form of term to indicate the recipient of the machines?
A. Yes; who either distributes them or uses them in any way, that is usually done.

Mr. Pemberton:
That is all.

Re-Direct Examination.

By Mr. Goodrich:
Q. Do you know of your own knowledge whether some of these machines were actually distributed to patients by sale and rental?
A. Yes, sir.

Re-Cross Examination.

By Mr. Pemberton:

Q. Just what do you know in that respect? You testified a moment ago of one machine being rented; is there anything beyond that?

A. Yes, one machine was rented to the Hoefker family, and I visited the Hoefker family to verify that; and there was a machine at the Feld family and I visited that family and verified that; and another machine was sold to the Deitz family and I visited that family to verify that fact.

Q. Do you have those dates, or anything?

A. I can get the dates.

Q. That's all right, we will pass it over for the time being. That's all.

(Thereupon, the witness was excused.)

O. O. ROWLAND was called as a witness on behalf of the United States and testified as follows:

23 Direct Examination.

By Mr. Goodrich:

Q. State your name and address.

A. O. O. Rowland; Cincinnati, Ohio.

Q. What is your occupation or profession?

A. Head Trace Clerk, Railway Express Agency.

Q. Are you appearing here in response to a subpoena duces tecum?

A. Yes.

Q. Do you have the records of the Railway Express Agency called for in the subpoena?

A. I have.

Q. Will you let me see them, please?

(Witness hands records to Mr. Goodrich.)

Q. Are these records that you have given me the original records of the Railway Express Agency?

A. Yes.

Q. Will you tell the Court how those records are routinely made?

The Court:

That is not necessary; the only purpose is to show a date.

Mr. Goodrich:

The only purpose is to show they were made in the regular course of business. I think we can take notice of that. We offer them in evidence as Government's Exhibits Nos. 7 to 11 inclusive.

Mr. Pemberton:

No objection.

(Same are so marked and filed in evidence.)

The Court:

I don't see where the dates are material. He admits the interstate shipment in interstate commerce.

Mr. Goodrich:

It may have some materiality as to accompanying the shipment. May I have the record show that these exhibits which have been marked show the following shipments: 7/25/45, Railway Express, No. 28-16-38, value, $3500.00, from Dr. Urbuteit to Dr. J. J. H. Kelsch; same date, No. 28-16-39, value, $800.00, same shipper and same consignee; 8/14/45, No. 83-88-35, value $1200, same shipper and same consignee; 8/18/45, No. 28-16-50, value, $800.00, same consignee, shipper being Lee Terminal & Warehouse Corp.; 9/21/45, No. 85-44-69, value, $1200.00, same consignee, same shipper.

Cross Examination.

By Mr. Pemberton:

Q. Are those the original shipments and not the record of receipts in Cincinnati?

A. That is the original record that was made at the forwarding office and the delivery record at Cincinnati.

Q. Does this contain both?

A. It is all one.

Q. It shows the shipment and the receipt?

A. That's right.

Mr. Pemberton:

That's all.

(Thereupon, the witness was excused.)

DR. J. J. H. KELSCH was called as a witness on behalf of the United States and testified as follows:

25 Direct Examination.

By Mr. Goodrich:

Q. State your name and address, please.

A. Joseph H. Kelsch; 2421 Ashland Avenue, Cincinnati 6, Ohio.

Q. What is your occupation?

A. Chiropractor and Naturopath.

Q. Did you in June, 1945, go to Tampa, Florida and take training under Fred Urbuteit?

A. I did.

Q. Do you remember when you came to Florida for that purpose?

A. Some time in June; I don't remember the exact dates.

Q. How long did you study under Mr. Urbuteit?

A. About three weeks there.

Q. Will you tell the Court what course of study you pursued at that place?

A. Mostly clinical work; clinical with some patients that we have there.

Q. By "clinical work", explain what you mean by that.

A. We had some patients under treatment; the times some patients came in he demonstrated his method of diagnosis and treating.

Q. You took the course for three weeks?

A. Three weeks. We were there three weeks.

Q. Were you awarded a diploma as a result of your training there?

A. The diploma was awarded in absentia.

Q. Do you have that diploma with you?

A. I have. (Produces diploma.)

Mr. Goodrich:

I don't like to have this diploma marked; we have a photostatic copy we can put in evidence if it is satisfactory.

Mr. Pemberton:

The photostat is all right.

The Court:

You may file it in evidence if you want to and then substitute the photostatic copy.

(Diploma is filed in evidence as Government's Exhibit 12, with leave to substitute photostatic copy.)

Q. Are you the Dr. Kelsch mentioned in this letter that has been introduced in evidence, entitled, "Dear Patient", signed by Dr. Urbuteit, same being Exhibit 3?

A. These were sent to the patients.

Q. Now, can you tell us how these pads are applied to patients in giving your treatments, according to what you learned in the course of your studies?

A. Well, the pads were placed two side by side, either on the front of the body or on the back of the body.

Q. Were they placed on any particular position on the body?

A. They were usually placed directly over organs where pain was manifested; placed right over the area, side by side, through the torso of the body or the back.

Q. How were they placed when treating the area of the head, or arms, or legs?

A. One on the back of the head and one in the front of the head; and through the arms, we didn't have no demonstration there on that part; but we did treat one pad on the back of the arm and one on the front of the arm.

Q. Did you receive any written instructions as to where the pads should be placed?

A. No.

Q. Could you tell us how the patient's diagnosis is determined from the master machine, that is, the one that has the dial?

A. Well, I could not say positively, to make a diagnosis from the machine, that I personally make one.

Q. Do you mean that you are unable to diagnose with these large machines?

A. That's right.

Q. Were you supplied with any readings from Dr. Urbuteit which would indicate the conditions of disease present in patients; any readings on the dials of the larger machine?

A. None that I could say, with the exception of possibly through increased sensitiveness a patient would state that they felt that pressure was put on the pad;

otherwise, I could not say anything about diagnosing it.

Q. When Dr. Urbuteit demonstrated diagnosis to you, did you observe the readings on the dials at any time?

A. Yes.

Q. Did you have any information as to what a particular reading would mean, as to whether a patient was diseased, or in a perfect condition?

A. Well, I believe that when the pads were applied to a particular spot where he diagnosed that more sensitiveness was manifested on the dials, as far as I could understand.

Q. And you don't have any figures you could give us as to what those dials should read to indicate a particular condition?

A. No, I have not.

Q. In the method of diagnosis which he demonstrated to you, was it similar as to what is known to you as "palpation"?

A. Yes.

Q. Will you tell the Court what "palpation" is, in the diagnosis of disease?

A. Most particularly, palpating the liver or gall bladder area which he demonstrated mostly is the lower portion of the liver would show out below the ribs and the gall bladder could be palpated from the lower part of the ribs, below the ribs, and if there was a sensitive spot there in the center of the ribs that would be an inflammation or congestion of the gall bladder, is the way it was demonstrated to me.

Q. Do you know whether or not it is possible by a palpation with the hand alone to feel those sensitive spots?

A. Well, I could say that sensitiveness was there; the patient would say that he felt a sensitiveness upon pressure.

Q. Is pressure applied to the electrodes when he is palpating for diagnostic purposes?

A. Well, the patient might demonstrate sensitiveness more by the pad due to the penetrating effect, possibly; or due to the different effect of the electrical process the patient would feel it possibly more than if palpated by hand.

Q. What I would like to know is, when the pads are applied to the body for diagnostic purposes was pressure necessary upon either or both of the pads?

A. Yes, there was pressure there.

Q. While you were in Tampa, Florida, did you make arrangements with Dr. Urbuteit to obtain some of these machines by a purchase and by lease?

A. We were considering, but nothing definitely was made out of it.

Q. Is it a fact that arrangements were made contingent upon your making the financial arrangements necessary in Cincinnati?

A. That's right.

Q. Did the devices involved in this case come from Dr. Urbuteit to you by shipment?

A. Yes.

Q. Did you purchase some and rent others, or did you buy them, or how?

A. I purchased some, and others I rented.

Q. While you were in Florida did you discuss with Dr. Urbuteit the question of supplying you with leaflets which would explain these machines to your patients?

A. I did.

Q. And what was the nature of that leaflet?

A. "The Road to Health."

Q. Did you thereafter receive the leaflets from Dr. Urbuteit?

A. We received leaflets after the machines were delivered; that is, they shipped them to us.

Q. Can you tell us how those leaflets were received; were they received in bulk supply to be mailed out by you, or received in some other form?

A. They were received in a bulk supply and we mailed them out.

Q. Did you have an understanding with Dr. Urbuteit about this mailing of the leaflets?

A. Yes.

Q. Did you show these leaflets to any of your patients at the time of consultation?

A. Yes, I showed some of them.

Q. Were some of these machines used by you in your practice prior to the seizure?

A. Yes.

Q. Did you sell some of the devices?

A. Yes.

Q. Did you give your patients any instructions as to how the devices should be used?

A. Well, there was a diagram illustration.

Q. I hand you this—

A. This is it.

Mr. Goodrich:

We offer this in evidence as Government's Exhibit No. 13.

Mr. Pemberton:

No objection.

(Same is so marked and filed in evidence.)

Q. Now, how did you indicate to your patients where the pads should be placed by the use of this diagram of the human body?

A. Well, while I was in Tampa, under Dr. Urbuteit, he instructed me where those pads should be placed in

various conditions; and, of course, I marked those illustrated diagrams out to those patients that rented machines.

Q. I show you a sheet which purports to duplicate certain treating cards given to Mr. and Mrs. Hoefker; will you tell me whether those "X" marks I see on that represents where the pads should be placed?

A. Yes.

Q. Did you sell some of the devices too?

A. Yes.

Q. Did you receive the leaflets while you were at Tampa, the bulk supply, or were they shipped to you in Cincinnati?

A. They were shipped to me.

Q. Do you know what time they were shipped, the approximate time, or the exact time?

A. I don't know the exact date, but they were received some time around September; I can't exactly say what exact time.

Q. Where were they received from?

A. Received from Tampa, Florida.

Mr. Goodrich:

We offer in evidence the duplication of treatment cards identified by the witness, as U. S. Exhibit No. 14.

Mr. Pemberton:

No objection.

(Same are marked and filed in evidence.)

Cross Examination.

By Mr. Pemberton:

Q. I believe you stated they were received after you received the machines?

A. Yes.

Q. You stated, did you not, in your examination in chief, that you are a naturopathic and chiropractic physician, practicing in Cincinnati, Ohio?

A. That's right.

Q. How long have you been practicing there?

A. About twenty-six years.

Q. And you are licensed in that State?

A. No.

Q. In Cincinnati, Ohio, to practice your profession?

A. No.

Q. Explain what you mean by the fact that you are not licensed?

A. When I came to Cincinnati twenty-six years ago my brother, named John Kelsch, and myself, we decided to settle in Cincinnati and start a practice. My brother John, he took the Ohio State examination and it was not necessary for me to take an examination because I was practicing under my brother John. We were practicing eight years there.

Q. Then you never took an examination after that?

A. No.

Q. But you continued to practice?

A. When my brother John died I continued in the practice just like under him.

Q. But you have been actually in the practice there then for twenty-six years?

A. That's right.

Q. Did you receive some training before you went into that actual practice, at some college or school?

A. Yes, I attended the Lindlahr College of Naturopathy, and the Palmer College of Chiropracty, in Chicago, for three years.

Q. You are operating now in the same location that you have been prior to the time you visited Dr. Urbuteit?

A. The same location.

Q. What you took from Dr. Urbuteit did not purport to be a fundamental course in the healing arts, or medical training, but a short course in the use of the particular device that he manufactured; is that correct?

A. That's right.

Q. He was not attempting to teach you to be a doctor, in other words?

A. No.

Q. You had been in actual practice for many years?

A. Yes.

Q. How long did you have the machines in use before they were seized by the Federal Government?

A. Well, they were somewhere around two months; I don't believe it was quite two months.

Q. During that period did you treat your patients who came to you, with the machines?

A. I treated some of them, yes.

Q. Not all of your patients, but a part of them.

A. No.

Q. What did you find to be the result of the use of the machine?

Mr. Goodrich:

Object; it is outside of the scope of the direct examination. He can call this witness as his own.

The Court:

Objection sustained.

Q. You received these machines as a doctor, for use in practice, and not as a merchant, for sale and distribution; did you not, Dr. Kelsch?

A. I don't understand what you mean.

Q. Are you in the business of selling therapeutic devices?

A. No.

Q. Did you receive these machines as a merchant, or as a practicing physician?

A. I received them as a practicing physician.

Q. What, then, was the occasion or the reason for the sale of one of the machines?

A. Well, Dr. Urbuteit said that some of those that were out of the city and wanted a machine, they could purchase it, and as he did in his practice; so I sold some of them that went out of the city.

Q. That was because these people were not living in your locality, where they could take regular treatments from you; is that it?

A. That's right.

Q. And the machine was sold to them in order that they might have the use of it, although they were away from Cincinnati?

A. That's right.

Mr. Pemberton:

That's all.

Re-Direct Examination.

By Mr. Goodrich:

Q. Doctor, when you were taking this course under Urbuteit. did you have any books or any lectures of any kind teaching you the theory and practice of this machine; or did that course consist only of observing the use of this machine?

A. Observing.

Q. How did you diagnose diseases after you obtained these machines?

A. Like I usually did; laboratory; a case for the laboratory diagnosed by X-ray, or whatever the case was indicated for.

Q. You stated that you made no sales of these machines in the locality where you are located; isn't it a fact that you sold one to a man in the City of Cincinnati that had a duodenum ulcer?

A. No, I didn't sell one in Cincinnati, unless it was Greater Cincinnati, Kentucky.

Q. With the instructions which you gave to the Hoefkers, which has been introduced into evidence, do you believe they were capable of using the machine with satisfactory results?

A. The Hoefkers lived in Kentucky and they took treatments in the office and after they had a number of treatments they decided they wanted a machine for their home use; and, of course, I gave them one of the illustrations on how to apply the pads.

Mr. Goodrich:

That's all.

(Thereupon, the witness was excused.)

36 MRS. JOSEPH H. KELSCH was called as a witness on behalf of the United States and testified as follows:

Direct Examination.

By Mr. Goodrich:

Q. State your name and address, please.

A. Mrs. Joseph H. Kelsch; 2421 Ashland Avenue, Cincinnati, Ohio.

Q. I show you Railway Express Receipt No. 83-88-35 and ask you if that is your signature on the bottom.

A. Yes, it is.

Q. I show you a receipt No. 28-16-38 and ask you if that is your signature on that?

A. Yes, that is my signature.

Q. I show you Receipt No. 28-16-39, Government's Exhibit No. 10, and ask you if that is your signature.

A. Yes, that is my signature.

Mr. Goodrich:

I would like the record to show that the other two exhibits referred to are U. S. Exhibit 11 and U. S. Exhibit 8.

Q. Were the machines which were seized from the office of Dr. Kelsch those which were received by you and for which you signed these receipts?

A. Yes, they were.

Mr. Goodrich:

That is all.

Mr. Pemberton:

No questions.

(Thereupon, the witness was excused.)

37 PROFESSOR W. C. OSTERBROCK was called as a witness on behalf of the United States and testified as follows:

Direct Examination.

By Mr. Goodrich:

Q. Will you state your name and address for the record, please?

A. Wm. C. Osterbrock; 1549 Whittlou Avenue, Cincinnati, Ohio.

Q. What is your occupation?

A. Professor of Electrical Engineering at the University of Cincinnati..

Q. Do you hold any other position in the Department?

A. I am head of the department.

Q. What degrees do you hold?

A. The Degree of Electrical Engineering, in 1918.

Q. What faculty appointments have you had since graduating from school?

A. I have been successively, Instructor of Electrical Engineering, Assistant Professor, Associate Professor, and Professor of Electrical Engineering. The last appointment was in 1937; and since 1942 I have been Head of the Department.

Q. Are you a member of any professional or honorary societies?

A. Honorary Societies. Tau Beta Pi, Honorary Engineering Society; Sigma Si, Honorary Research Fraternity; Eta Kappa Nu, Honorary Electrical Engineering.

Q. Now, professional societies—.

The Court:

I think the witness is qualified.

Q. Have you, since your graduation, ever had occasion to work in industry on therapeutic machines of any kind?

A. Yes; I spent one summer in the employ of Liebel-Flaschen Co. They manufacture diathermy, X-ray and other kinds of physical therapeutic apparatus.

Q. Have you examined the device known as "Sinuothermic"?

A. Yes; two models; one large one and one small one.

Q. How did you come to examine these devices?

A. They were brought up to the University by Mr. Ahlmann, a representative of the Food and Drug Adminis-

tration; and I examined them at the request of Dr. K. L. Milstead, of the Cincinnati office of the Food and Drug Administration.

Q. Did you open the device and examine all parts, individually?

A. I did.

Q. Did you make a diagram of the electric set-up of these machines?

A. Yes, I traced all the wiring and then made a diagram showing how the connections were made.

Q. Could you state whether or not this (indicating) is a duplication in large scale of that diagram?

A. Yes, it is.

Q. Does this truly represent the electric circuit involved in these machines?

A. It does.

Mr. Goodrich:

Government offers this diagram in evidence as U. S. Exhibit No. 15.

Mr. Pemberton:

No objection.

(Same is so marked and filed in evidence.)

Q. Did you make a photograph of the transformer of the machine?

A. I did.

Q. I show you this photograph and ask you to identify it.

A. That is my photograph of the transformer.

Q. Does this truly represent the transformer found in the machine?

A. It does.

Mr. Goodrich:

We offer this photograph in evidence as U. S. Exhibit No. 16.

Mr. Pemberton:

No objection.

(Same is so marked and filed in evidence.)

Q. Now, will you describe the construction of the larger model of the machine which you examined.

A. The larger model consists of a number of electrical parts mounted in a wooden cabinet. The electrical parts include the line cord, a line switch, a potentiometer or voltage divider, a step-down transformer, four meters, indicating meters, and a pair of output terminals, a pair of flexible leads extending from the output terminals to the output pads.

Q. Will you show this Court how this diagram represents the electrical construction?

A. This (indicating) represents the line cord, and this (indicating) is the line switch; No. 1 is the A. C. alternating current volt meter; this (indicating) is the potentiometer or voltage divider, with its slide or tap.

Q. Tell the Court what that is for.

A. The function of the potentiometer is to reduce the voltage applied to it by an adjustable amount. The construction of the potentiometer is a coil of resistence wire with a slider or tap that can be adjusted and as the tap is moved the voltage is reduced from the original value of the line voltage to any desired value from zero up to the full line voltage. No. 1 is the alternating current volt meter which reads the voltage.

Q. Do you mean by that the voltage that comes out of the power house of the City?

A. The same voltage as applied on the lights in the room. No. 2 is another electrical volt meter; it reads the voltage which is voltage at the output of the potentiometer, which consists of two coils of wire, the windings of which are coupled together by magnetic induction, and its function is to reduce the voltage applied at the primary terminals by a fixed ratio so that the voltage on the secondary is lower than that on the primary. No. 3 is the A. C. ammeter which measures the current flowing from the secondary of the transformer; and No. 4 is the A. C. volt meter which measures the voltage across the output terminals.

Q. The output terminals, what are they in this machine?

A. From the output terminals flexible leads extend to a pair of contact pads which are placed in contact with the body.

Q. Now, when the pads are placed upon the body what happens to the electrical current there?

A. Coming from the outlet socket through the line cord the current is 60 cycle alternating with a sinusodial wave form, of approximately 115 or 120 volts.

Q. What do you mean by "sinusodial wave form"?

A. Sinusoidal wave means having the form of a sine curve or a simple wave. This (indicating) is a sketch of the sinusoidal wave, the current alternately flowing first in one direction and then in another; and this represents its variation in time.

Mr. Goodrich:

We would like to have that offered in evidence as U. S. Exhibit No. 17, which is the Sine Curve.

Mr. Pemberton:

No objection.

(Same is so marked and filed in evidence.)

A. The current then flows through the potentiometer and there the voltage is stepped down, depending on the position of the slider which is controlled by a dial on the front of the cabinet. That voltage can be set to any value from zero up to any voltage to 115 to 120 volts. The voltage is read by meter No. 21. Then the current flows through the primary winding of the transformer.

Q. Will the current flow through the primary winding of the transformer without placing the pads upon the patient?

A. A small amount; but largely current will flow when the pads are placed in contact. The current flowing in primary steps up by induction the voltage in the secondary and it is smaller than the voltage indicated in meter No. 2; then the current flows through the ammeter, No. 3, and through the output terminals, through the flexible leads and to contact pads, and the circuit is complete.

Q. Does it flow through the body there?

A. It flows through the body between the two points where the contact pads are applied.

Q. Now, will you explain the difference between voltage and current, so that will be straight in the record?

A. The voltage is electrical pressure or driving force; it is analogous to fluid pressure in the hydraulic system. Current, or amperage, means rate of flow of electricity and it is analogous to fluid flow in the hydraulic system.

Q. Will you describe the contact pads which were used with this machine for placing upon the body?

A. They consisted of a sheet of metal, covered on one side by rubber and on the other side by felt.

Q. Describe the size.

A. The size is approximately 4½ inches in length and three inches in width; roughly oval.

Q. Can you tell us what changes the amount of resistence in the external circuit; I mean when the pads are placed upon the human body?

A. The resistence between the pads depends on the distance between them and the surface conditions; that is, whether the pads are dry or moist, or the amount of contact pressure exerted.

Q. By contact pressure, do you mean you can change the amount of body resistence by exerting physical pressure on the body of the contact pad?

A. Probably not the body resistence, but the resistence of the pads would be affected that way.

Q. Is there any change in the resistence due to the conditions of the skin?

A. Oh, yes; if there is a cut or scratch or other opening in the skin the resistence would be very much reduced because the major portion of the resistence is at the skin surface.

Q. And how will that be reflected on any of these diagrams?

A. Well, they lower the resistence; the reading of ammeter No. 3 will be higher and the reading of volt meter No. 4 will be lower; that is to say, the lower the resistence the greater will be the reading of No. 3 and the smaller the reading of No. 4 for any given setting of the potentiometer dial.

Q. And will those dials change any actually because of skin conditions, be lowered because of the conditions of the electrodes; that is, by moistening of the electrodes?

A. Yes; if the electrodes are dry the resistence will be higher, and if moist the resistence will be lower. Also, resistences are different as between individual persons, considerably different.

Q. How does this current coming out of the machine compare with ordinary current delivered from the wall socket?

A. It is exactly the same form sinusoidal alternating current; the frequency is 60 cycles per second; the only difference is that the voltage is lower.

Q. Is the current delivered by either of these machines in any way magical or mysterious?

A. No, no more than the current flowing through our lights here.

Q. Do all four of the meters change when the pads are applied to the body?

A. Maybe No. 1 will not change at all; maybe No. 2 will change very slightly; the only one that changes most is No. 3; and No. 4 will change to some extent.

Q. Now, then, what causes these meters to change their reading; what would cause them to move?

A. Variation of the potentiometer setting will cause Nos. 2, 3 and 4 to change, and variation of the resistence through the path in the body will cause them to change. Now the reasons for change in the body path I think I have already mentioned, that is, the proximity of the electrodes, the pressure applied and whether they are are moist or dry.

Q. What path does the current from the two electrodes pads follow through the body?

A. The current always follows the path of least resistence, and in the case of the body that means through the body fluids, definitely, because they are the best conductors of electricity.

Q. Where is the major part of the resistence to this current in the body?

A. The major part occurs at the skin surface.

Q. After the electrodes have broken through the skin resistence they move from electrode to electrode and in the shortest course or through the course of least resistence.

Q. In what respect does the small machine differ from the large machine?

A. Only in the omission of the four indicating meters; the other electrical parts are exactly the same and the output is of the same form.

Q. Is the current delivered by these machines different in any way from the current delivered from diathermy machines?

A. Oh, yes. The diathermy machines always include a generator of high frequency currents, the frequencies in the case of diathermy ranging from 500,000 cycles per second to several million cycles per second; while the frequency here is always 60 cycles per second. The high frequency currents do not produce electrical shock and so it is possible to pass very large currents through the body, large enough to produce internal heating; whereas in this case the currents must be limited to a much smaller value for safety, and they are so small that they cannot produce an appreciable amount of heating in the body.

Q. Does the milliamperemeter register accurately any amount of current less than 20 milliamperemeter?

A. No. It has a full scale reading of 100 milliamperemeters and A. C. ampers, and volt meters are not reliable below twenty percent of full scale reading.

Q. What would 20% of full scale value be?

A. In this case, twenty milliamperemeters.

Q. As an electrical engineer interested in the design of mechanical circuits, what milliamperemeter generally is considered safe to come in contact with humans?

A. Twenty milliamperemeters is regarded as the absolute maximum that can be tolerated with safety.

Q. Can you tell us what the ordinary range—I mean the minimum and maximum figure—of body resistence is?

A. It is quite variable, but for the usual circumstances it ranges from something over one thousand ohms to three thousand ohms.

Q. By fixing a determined resistence between the two output terminals indicated on Government's Exhibit No. 15, is it possible to calculate what the readings of milliamperemeter reading No. 3 and volt meter No. 4 would be at all times?

A. Yes. Of course, the setting of the potentiometer would also have to be known.

Q. Let's assume a maximum setting of the potentiometer—.

The Court:

Is it necessary to go into this line of examination?

A. It is possible to detect the readings of meters Nos. 3 and 4 for any specific value of resistence connected between the pads when the potentiometer is set at its maximum value.

Mr. Goodrich:

That is all.

Cross Examination.

By Mr. Pemberton:

Q. Doctor, I wish you would describe the construction of the transformer that you have shown on that diagram there on the machine that you examined.

A. The transformer consists of two windings of insulated wire. There is an ordinary machine volt passed through the center of the windings and the windings are covered with a layer of material, I believe Empire cloth; and the whole thing is installed in a plywood box and sealed in a tar or pitch compound.

Q. Are all transformers made that way?

A. Oh, no. There are a great variety of constructions for transformers.

Q. What is the reason for that?

A. Well, each design is suited to its own particular purpose.

Q. Aren't they just plainly to reduce or increase the current or anything else?

A. In the case of a distribution transformer it is very important to have high efficiency and low core loads, and there would be a very much laminated steel core of carefully selected steel. And in the case of an amplifier, the requirements are that it must pass a wide range of frequencies, which is not true in the case of a distribution transformer. For a high voltage transformer the insulation has to be very carefully selected so as to prevent electrical breakdown.

Q. Are windings made in the same manner, or do they vary in the different ones?

A. They vary in type and construction.

Q. They vary in the type and construction and machines?

A. Yes.

Q. There is practically no limit to the general construction in what we call a "transformer"?

A. I think that is a fair statement.

Q. Both as to coil and windings and number of turns, etc.

A. That's right.

Q. These various things create different electrical effects, if I may use the term "effects" as a general term.

A. I would not like to make that too general. The only function that a transformer can fulfill is to make a change in the voltage ratio and current ratio. It does not change the frequency and it does not change the wave form.

Q. The wave form never changes?

A. Well, that requires some modification too; because of the saturation curve of the steel and iron that is used for the core there may be a slight modification of the wave form.

Q. As far as you got into this transformer—I assume this (indicating exhibit) is that picture—is what is disclosed by the picture there?

A. Roughly, what I have told you; yes.

Q. From that were you able to determine the exact make-up of the windings and the entire construction of it?

A. No.

Mr. Pemberton:

No further questions.

Re-Direct Examination.

By Mr. Goodrich:

Q. Did you apply recognized physical tests to the output of this machine in determining exactly the nature of the current coming out?

A. Yes, I measured the voltage and current with accurate meters, not relying on the readings of the meters installed, since they are guaranteed to only 2% precision; and in addition I connected a cathode ray oscillograph—.

Q. Tell the Court, briefly, what that is.

A. A cathode ray oscillograph is an instrument which makes it possible to observe the wave form of a voltage or current applied to its terminals. This wave form appears graphically present on the screen of the instrument. As I say, I connected such an instrument to the output terminals and the voltage and current wave forms were, as nearly as I could tell, pure sinusoidal wave forms, 60 cycles frequency.

Q. Regardless of any winding or alteration in the current, in the step-down transformer would that be evidenced by the showing upon the face of the cathode ray oscillograph?

A. Yes, the wave form I observed was that of the output terminals, so if a transcript appeared it would make no difference on the instrument.

Mr. Goodrich:
That is all.

Re-Cross Examination.

By Mr. Pemberton:

Q. That was generally the form of it?

A. That was as closely as I could determine and that was nearer than 2%.

Q. I don't believe you have explained exactly what is meant by this "wave form".

A. All right. The current, as I show on the sine wave, first of all, according to this diagram, the current flows first in one direction and then in the other. Now this (indicating) represents graphically that variation; the horizontal axis represents the dial, and the vertical axis represents the value of the current. When the current is flowing in one direction in the circuit it is defined as "positive", and when flowing in the other direction it is defined as "negative". So this curve shows that the current starts at zero and increases positive to a maximum and then decreases to zero and then becomes negative. That means the current's direction is reversed and increases to the negative maximum just the same as the previous positive maximum, and then again decreases to zero. Now that constitutes one cycle, and, as I have said, there are 60 of these cycles in a second; that is, there are 120 reversals of direction in a second. In the case of a diathermy machine there would be millions of these cycles per second. That (indicating) is a general form known as a "sine wave", which would vary in the degree of its up and down motion, if you draw it as a curve.

Q. You have a wave for voltage and for current?

A. They are exactly the same.

Q. And then when you make all transformers they run on the same things.

A. That's right. Except for this change that I mentioned earlier, of the magnetizing current. Its wave form may be slightly disturbed from the sine curve, but no such effect was observed on this machine.

Mr. Pemberton:
That is all.

(Thereupon, the witness was excused.)

51 PROFESSOR DANIEL RUSSELL McMILLAN, JR. was called as a witness on behalf of the United States and testified as follows:

Direct Examination.

By Mr. Goodrich:

Q. State your name and address, please.

A. Daniel R. McMillan, Jr.; 1319 Emory Circle, Atlanta, Georgia.

Q. What is your present occupation or profession?

A. Professor of Physics and Chairman of the Department of Physics at Emory University.

Q. What are the duties of your position?

A. Teaching courses in undergraduate and graduate physics and supervising instruction and laboratories in the Department of Physics.

Q. Will you give a brief statement of your educational attainments and experience since leaving school in the field of examination of electrical equipment.

A. B. S. Degree in Mechanics from Georgia School of Technology, and a Master's Degree of Physics from Emory University, and a P. H. D. in Physics from University of N. Carolina. For the past thirteen years I have been associated with the Department of Physics at Emory University. That about completes it.

Q. Are you a member of any professional or honorary societies?

A. Yes.

The Court:

I think the witness is qualified.

Q. Have you had occasion to examine the device called, "Sinuothermic"?

A. Yes, I have.

Q. Did you test the in-put electricity and out-put electricity of the machines?

A. Yes; I tested the in-put and out-put voltages and currents.

Q. Are you familiar with the testing apparatus known as the cathode ray oscillograph, or oscilloscope?

A. Yes.

Q. Is it a standard piece of testing equipment used by physicists in testing unknown currents?

A. Yes.

Q. Will you tell the Court what you found of the in-put electricity upon these machines, and the out-put, by these tests?

A. With the oscilloscope, I checked the form of the wave, form of the current, in-put and out-put of the machine, and found those to be identical. So far as the other measurements were concerned, I measured the voltage in-put and voltage out-put of the machine.

Q. And what results did you get from those measurements?

A. Would you like to know the voltages?

Q. Yes.

A. The voltage applied to the in-put is the same as the house wiring current and voltage; that is, a maximum of approximately 120 volts. The out-put can be varied from zero to 60 volts.

Q. Just what does this machine do to the ordinary wall current which advances through it?

A. Other than transmitting the voltage, stepping-down the voltage, there is no alteration.

Q. Government's Exhibit No. 15 has been explained in some detail by the witness who preceded you. Upon the basis of your examination of these machines, would you say that this exhibit accurately reflects the electrical apparatus in the large machine?

A. Yes, I would say so.

Q. Is the current delivered from either of the machines in any way mysterious or magic?

A. No.

Q. What makes the readings on the volt meters change?

A. The reading on volt meter No. 1 is the same as the voltage of a house wiring circuit; the voltage on meter No. 2 changes when the potentiometer is varied; the voltage on meter No. 4 is stepped down by means of this transformer and, of course, that also varies when the potentiometer setting is varied.

Q. What does the milliamperemeter show?

A. The milliamperemeter shows the current that passes through the electrodes and external circuit.

Q. By "external circuit", you mean the body when the electrodes are applied to the body?

A. Yes.

Q. If a physicist wanted to measure accurately any small changes in the difference in the external circuit, would he use an ordinary ammeter, or are there more delicate and precise instruments for making such measurements?

A. There are more precise instruments for making such measurements. The ordinary volt meter and ammeter would be used when rather a rough approximation of resistence is to be determined.

Q. Is the body electrical resistence of all persons the same?

A. No.

Q. Is the body electrical resistence of a single individual always constant?

A. No.

Q. Are the differences in body resistence reflected in the readings of the milliamperemeter No. 3 and the volt meter No. 4 shown on Government's Exhibit No. 15, when the electrode pads are applied to the body and the current turned through the machine?

A. The resistence can be determined from the reading of those two meters.

Q. Is it possible to predict with any degree of accuracy what a person's resistence would be at any given time?

A. No, I should say not.

Q. Why not?

A. Well, the resistence of the body of a given person offered to the electrical current would depend on the conditions of the skin; it would also depend on the pressure wtih which these electrodes are applied; and, of course, on the distance of separation between the electrodes, or the distance or path that the current has to flow.

Q. What do you mean by the "condition of the skin"?

A. I would say whether or not the skin is moist or dry, or the condition of cleanliness of the skin; whether there are cuts or other abrasions on the skin.

Mr. Goodrich:

That is all.

Cross Examination.

By Mr. Pemberton:

Q. I want to ask you a question. It is not actually in cross of anything. Are you acquainted with the Dean of the Emory University Medical School?

A. Yes, I am.

Q. You are not in the Medical Department?
A. No.
Q. What is his name?
A. Dr. Hugh Wood.
Q. At the present time?
A. Yes.
Q. How long has he been there?
A. He has only been Dean for a short length of time.
Q. Who was the one previous to him?
A. Dr. Oppenheimer. There was an Acting Assistant Dean between the retirement of Dr. Oppenheimer, and that was Dr. Stubbs.

Mr. Pemberton:
That is all.

(Thereupon, the witness was excused.)

55 DR. JOHN HALDI was called as a witness on behalf of the United States and testified as follows:

Direct Examination.

By Mr. Goodrich:
Q. State your name and address for the record, please.
A. John Haldi; Emory University, Georgia.
Q. What is your occupation or profession?
A. Professor in the Medical School, Emory University, and research investigator.
Q. What courses do you teach in the medical school?
A. Physiology to the medical students.
Q. Will you give a brief summary of your training in the field of physiology?

A. I got a P. H. D. Degree in Physiology in 1923; and I have been teaching physiology and doing research investigation for most of the time since then. For the last thirteen years I have been Associate Professor of Physiology at Emory University; and before that I was Instructor and Associate Professor at the University of Michigan in the Medical School there.

Q. Do you belong to any professional societies in the field of physiology?

A. American Physiological Society, belonged for a number of years; I belong to the American Association for the Advancement of Science; and the Georgia Academy of Science.

Q. Have you made any contributions to the scientific literature in the field of physiology? If so, what?

A. Yes, I have published over thirty papers in the American Journal of Physiology; American Journal of Nutrition; American Journal of Gastrology.

Q. Will you tell the Court just exactly what physiology is?

A. Physiology is the science which studies the functions of the individual organs and the intra-relationships of those organs one with the other.

Q. Can you describe in a general way how the physiological investigations or studies are made in the laboratory?

A. Of course, we have to work out a particular technique for a particular problem, but in general I may say that we experiment on animals, studying the various functions of the body and the organs of the body. We use animals, and of course, we use men; as a matter of fact, I have stated that the last three papers I have published have been studies made on men. We use animals to a large extent because it is obvious in certain types of experiments you cannot use men; the experiments may be dangerous; maybe involve operations; and we find that

in most cases the functionings of the animal organs, what we learn about the functioning, can be applied to men. For example, we have learned about diabetes mellitus by experimenting on animals; take out the pancreas of the animal and we get the same symptoms or group of symptoms in a dog that we get in a diabetic patient. And you can take the pancreas out of animals and obtain an extract from the pancreas and treat human beings with it. Similarly we can take the thyroid out of an animal and obtain extracts from the thyroid and treat patients whose thyroid gland is hypofunctioning; and when I say "treat" them, I mean treat them successfully.

Q. Hypofunctioning means under-functioning?

A. Underfunctioning of gland and the secretion not produced, unless the gland can be supplied by the same gland obtained from animals. Most of our knowledge of nutrition and vitamin deficiency has come from the study of animals. In most instances, or at least in a great many, we get the same nutritional deficiency in animals that we can get in men.

Q. Have you received and examined any device known as "Sinuothermic"?

A. Yes.

Q. From whom did you receive the devices?

A. From the Pure Food and Drug Administration.

Q. Are you acquainted with the physical nature of the current delivered from these machines?

A. Yes.

Q. Have you studied the devices in connection with their physiological effects, or the physiological effects they might be expected to produce?

A. Yes. We took these devices in the laboratory and made a number of studies.

Q. Will you describe as briefly as possible what those studies were?

A. Well, we used first of all, of course, we applied the electrodes to different individuals in the laboratory. We didn't make physiological studies on these individuals, for obvious reasons that will come out in the discussions. Frankly, we were afraid to. We don't take chances in experimenting with men, so we used the animals, rats and dogs. Would the Court like for me to explain those experiments?

A. Yes, briefly.

Mr. Goodrich:

Might I state that Professor Haldi has some diagrams showing the various physiological results of these tests, such as the results of blood pressure, heart action and respiration and other physiological effects that can be summarized, or he can show the Court what he has.

The Court:

He can testify what effect it had, without going through all that.

Q. Will you describe, without going into details on the diagrams, what physiological effects were seen from these machines from your tests.

A. Since it does not please the Court, I will not show these drawings. I brought them along to show how these experiments are conducted.

The Court:

If you can illustrate your testimony better, go ahead.

A. I don't want to impose on the Court.

Q. I think that may be stated by showing one and we will summarize the results.

A. I will show one and in fairness to the experiments, perhaps two, very briefly. In studying the respiration

we put an instrument around the animal's chest called a pneumograph, which consists of a wire spring covered with a thick rubber membrane so air cannot get into it. It is sealed on one end and on the other is a rubber stopper with a tube and that tube has a little tube on it, and sealed, and then there is a spring that goes around the animal so that when the animal breathes the spring will expand or contract, and attached to one end is a rubber tube which goes off on an instrument called a recording tambour, which moves up and down as the animal inspires and expires, so that we get this type of tracing. (Indicating on drawing.) As the animal inpires the chest goes up and as it expires it goes down. That (indicating) records the blood pressure, so we have the blood pressure; and you notice it goes up and down a little bit with each expiration and inspiration. And we measure the height of the blood pressure by getting the distance between this line (indicating) and this (indicating) and multiply it by two, and that give us the blood pressure in millimeters. Now we have done a number of experiments with animals and I might say that every one of the animals except one was killed by the instrument after we had obtained some tracings. The animals varied in their susceptibility to this current. You will notice here (indicating) that when an impulse was sent in that there was a little rise in the blood pressure, but there was a gasp upon the part of the animal and then irregularities in respiration. In some of them the animal stopped breathing altogether, as shown by this tracing. In others, with a slight amount of current there was a rise in the blood pressure followed by irregularities, or by a drop later. You will notice here the effect on the heart. Whenever the heart beats we get one of these little movements by a lever.

The Court:

Like an electrical cardiograph?

A. Something like that. Here when we sent in a current the lever was going up and down every time the heart beats—goes up a little bit life that—this shows that there is a marked effect upon the heart and at the same time a pronounced drop in the blood pressure. This animal took a considerable amount of current.

Q. Tell the Court how the pads were applied to the animal.

A. In different places. This animal had the pad applied on the back of the neck and one on the chest. Some of them had the pads applied on the right arm and left hind leg, and we shifted them around to different places. Here's another animal which was experimented on immediately after this first one. This one was pretty tough, as far as electrical current was concerned; took a lot of it. We took another animal, going along very nicely, breathing rhythmically, heart beat regular and blood pressure remained constant; and at this point we turned on the current and immediately the blood pressure dropped to zero and it took a big gasp and a few little gasps and then the animal is dead. Whenever the blood pressure goes down like that the experimenter knows he is through, the animal is dead. This animal was highly sensitive to the current and this one (indicating) could stand it. Some can take a considerable amount and others hardly any.

Q. The human subjects on whom you have tested the machine, could all of those subjects tolerate the same amount of current?

A. We did not measure the degree of tolerance, because we were not going to take a chance of killing a human being, but the resistance of these different individuals varied. By that I mean this: We would have a subject hold the electrodes in his hand and then we would turn the dial or knob on the larger instrument until we got a reading of 30 volts, and at that point most

subjects complained that they could not take it any longer. And we took the reading of the small dial showing the amount of current going through and with the same voltage we got a different reading for different individuals. The only way you can explain that is that the resistance of the skin of different individuals varies so that turning the knob to a certain point that tells a certain voltage would not send the same amount of current through every individual.

Q. Were any of the physiological effects that you observed in your animal experiments permanent, other than death?

A. No. That is, with acute experiments. By that I mean they lasted only a short time; but when the blood pressure rose after a slight stimulus being sent into the animal, in a very short time after that returned to its normal level. Except when it dropped to a very extreme degree it came back.

Q. Is there anything magic, miraculous or mysterious about the physiological effects of these devices upon the body.

A. No, not at all.

Q. What effect did the current, delivered by these machines through your experiments have upon the body; physiological effects?

A. The only effects that I can think of are the effects that it would have on animals. The animal's physiology would respond the same as of that of man. The blood pressure doubtless would be raised with a slight current and would be lowered, and even to dangerous limits, with a larger amount of current. The respiration might be stopped. As a matter of fact we have evidenced that in medical literature that when sending it through men the respirations sometimes are stopped and that constitutes a great danger, danger of asphyxiation. Another effect would be, it would stimulate the muscles to con-

tract and, of course, the tingling sensations that one gets become very painful if enough current is sent through.

Q. Can you feel the electricity which comes out of these electrodes when they are placed upon the body?

A. You get a sensation and I know that you are being stimulated. And I may say in connection with the contraction of the muscle that the muscles may become contracted and so taut that a person cannot let go of the electrodes. That, too, has been found to be a distinct danger unless the individual is watched very carefully.

Q. Are there variables on the surface of the skin that affect the resistance of the body, or affect the resistance of the skin to the passage of electric current?

A. Yes. The resistance of the skin varies under different conditions. The cleanliness of the skin would affect the resistance; the deposit of oily material on the skin, such as secretions by sebaceous glands; or the degree of moisture that might result from sweating; all those conditions affect the resistance of the skin.

Q. How does the skin resistance compare with the total body resistance to electricity?

A. The body resistance is relatively small as compared with the skin resistance. In fact, most of the resistance is found in the skin.

Q. What are some of the conditions which affect the moisture of the skin?

A. Emotional states will affect the moisture of the skin. We are always losing water from the skin. You can't always see it, so we speak of it as insensible perspiration, but we can show by various means that it is there. That insensible perspiration may be greater at times than at others. Emotional states will affect the degree of loss of water.

Q. Does that mean that the nervousness or apprehension which a patient may feel upon going to the doctor's office may affect the moisture of the skin?

A. Oh, yes; that is true. It is well known that anger, fear, apprehension and other emotional states do effect the degree of moisture on the skin, and incidentally the resistance of the skin to the electrical current.

Q. In your opinion as a physiologist, would it be possible to correlate differences in bodily resistance to an electric current with internal changes in the body due to pathological conditions?

A. No; that would be impossible.

Q. Why do you answer in that way?

A. For several reasons. A correlation of the resistance to the pathological changes would mean that with a given pathological change you would always have a given resistance; but you don't always have a given resistance in two different individuals in the same voltage as pointed out. Secondly, you don't have the same resistance of one individual in the skin at different times; as we have pointed out, the resistance might be affected by the moisture. And, thirdly, it would be assuming—the assumption is not correct—but assuming that the resistance within the body is affected by some change in the organ—. Let's take a concrete case. Suppose you had the electrodes over the kidney and suppose that there were a change in the resistance—. I say "change", but what norm do we have; we don't have any norm. We have an individual who came for examination, and assuming that the resistance were related to some pathological change in the organ, which we don't admit, but assuming all that, and you get what we call a change in the resistance, how could you tell whether that change is due to the hardening of the arteries of the kidney, or a stone in the kidney, or some pathological, some cancerous condition. So it is absolutely impossible, ridiculous, to assume that you can correlate changes in electric resistance in an individual with his pathological condition.

Q. What is the physiological disturbance which underlies the disease known as "diabetes mellitus"?

A. Well, the characteristic of that disease is the rise in the blood sugar and inability of the organism to utilize the sugar which is needed by every human organism. And in most cases that disease is brought on by degenerative changes in certain portions of the pancreas. The pancreas secretes a substance called "insulin", which controls this utilization of carbohydrates. And when this degenerative change takes place in the pancreas the secretion no longer gets in the blood and we no longer have that control over our carbohydrates; we have the rise in blood sugar and other conditions that we need not go into; symptoms that we refer to collectively as "diabetes mellitus".

Q. How is diabetes mellitus dealt with?

A. In view of what we said, one can readily see that the only rational treatment is to supply that which is lacking, and since insulin is lacking the only reasonable treatment is to supply insulin, and that is the usual treatment. We get the insulin from the pancreas of animals and inject it into man to make good for that which he does not have.

Q. Would the current from this device take the place of insulin in correcting the disturbance in any way?

A. Of course not.

Q. Would the current from this machine cause the pancreas to produce more insulin?

A. No.

Q. What is the physiological disturbance which underlies the disease known as "asthma"?

A. In asthma there is a constriction of the bronchials, which are small tubes in the lungs which deliver the air to the lungs; and that is why a person gasps, fights for breath, because the air cannot get down those tubes to his lungs. And that constriction of the bronchials is

due in many cases at least to what we call an allergic condition of an individual. He may be allergic to certain foods that he eats, or the dust in the air, or the feathers in the pillows. There are little proteins, it appears, that get into the blood and produce this constrictive action on the bronchials.

Q. Would the current from this machine in any way reduce a person's sensitivity to those factors to which he is allergic?

A. No.

Q. Would the current of this machine in any way alter or correct the physiological disturbance which underlies the disease called asthma?

A. Well, we found that if you send in current to these animals, that stops their breathing. It would not seem logical to treat a man who is fighting for breath by stopping his breathing.

Q. Is Addison's disease a glandular disorder?

A. Yes.

Q. What is the physiological disturbance which underlies Addison's disease?

A. Just above the kidneys there are two glands called the suprarenal or adrenal glands. These glands are made up of two parts; the outer part, called the cortex, or corresponding to the bark of the tree; and the inner part, or the medulla. The inner part produces a secretion which is different from the outer part. Sometimes the outer part undergoes degenerative changes. As the glands cannot secrete the hormone which it produces there usually results the very serious condition known as Addison's disease; and in this disease, which was usually fatal, however which now can be treated with some degree of success by the administration of the extract of the cortex—.

Q. What is that known as?

A. Cortin. In this disease there is also a current loss of sodium from the blood; gets out by way of the kidneys; and in the treatment of the disease it is necessary to administer sodium as well as cortin for best results. As a matter of fact, we can get pretty good results by the administration of sodium and carefully watching the patient.

Q. Would the current from this machine in any way overcome the deficiency of sodium or cortin encountered in Addison's disease?

A. It is impossible to believe that the deficiency of sodium in the blood can be made good by an electric current, or the deficiency of the secretion can be made good by an electric current.

Q. What changes take place in the arteries in the condition known as "hardening of the arteries"?

A. There is a calcareous deposition in the arteries. By that, we mean there is a hard material which is formed containing some calcium, hence we refer to it as calcareous, and this hard material is deposited in the walls of the arteries; consequently, the arteries lose their elasticity.

Q. Would the current from these machines make that calcareous substance appear from the arteries?

A. No. Unfortunately, it would not.

Q. Would the current in any way correct the underlying disturbance of the pathological condition known as hardening of the arteries?

A. It would not improve the disease. It might be dangerous by raising the blood pressure, and later on by lowering the blood pressure; either way.

(Thereupon, a recess was had until two o'clock in the afternoon, at which time Court reconvened and the fol-

lowing proceedings were had; the same witness on the stand:)

Mr. Goodrich:

I have no further questions of this witness.

Cross Examination.

By Mr. Pemberton:

Q. Dr. Haldi, you testified on direct examination this morning about some experiments on animals and showed charts regarding two of these. Just what type of animal did those refer to?

A. Those referred to dogs. I have stated that we also experimented with rats.

Q. You did make that general statement. I meant these specific ones.

A. Those are experiments on dogs.

Q. I wish you would describe just how you applied the current to those animals.

A. Well, we would attach the electrode shown in one experiment, one electrode to the hind leg and the other electrode to the front leg on the opposite side. Then in another experiment, to the front and hind leg on the opposite side. And then in another experiment the two sides of the chest, the right and left side. And in another one, on the back and on the chest. And so on.

Q. Just what electrodes did you use?

A. The electrodes you have there.

Q. With the machine?

A. Yes.

Q. You wet them, I presume?

A. Yes, I wet them. I didn't have these experiments in mind, but we also took smaller electrodes to see if we got the same result; and we did.

Q. How did you apply the current?

A. We applied the current, of course, you plug in from the wall current to the box and then the leads that come off the outlet there are applied to the electrodes and the electrodes, in turn, applied to the animal; and then we turned the knob that you see there on the small instrument and on the other instrument the knob that would allow the current to flow through.

Q. What I am aiming at, particularly, was the rapidity.

A. We did it, some we set it up slightly, and some by turning it on very rapidly. We did all types of experiments; some by turning it up a little and others where we turned it up all the way.

Q. What did you do when the animal you referred to was killed?

A. You mean what did we do with the animal?

Q. I mean what you did that brought it about; your use of the machine.

A. Well, every experiment that we did, except one, killed the animal. And usually it would take a pretty strong current to kill the animal; but in order that this statement might not be misleading to the Court, or to you, or to anyone else, I would like to take just a minute to say a word about the instrument. You notice that instrument over there with that one knob on it; that little bright thing that you see there is attached to the rod that goes in there by a little set screw. That little set screw holds it and moves the resistance. Would your Honor give me permission to go down and point out something on that?

The Court:

Yes.

(Witness leaves witness chair and steps over to where machine is placed.)

A. (Continuing.) We have instruments of this kind that has this type of knob in our laboratory, and after a while this little set screw, through use, may come loose; and when that happens you turn this knob and you get no effect because you don't increase the resistance. Now, it conceivably could happen, and would happen, in the use of this knob it would come loose at some time. Suppose somebody inadvertently would fool with the machine and turn it around like that (indicating), and then in doing so this knob would come loose. Well, we would have to put that knob back on, but the one that went to put it back on would not know the position of this arrow, and in putting it back on he might put the arrow pointing this way (indicating) and no matter how well trained your technicians are, and your nurses, and your laboratory assistants, you are going to have them get careless at times. They may be thinking about a date they have the next night, or what not, and get careless, and they might inadvertently loosen that knob and forget the position of the arrow; or they may not have known the importance of that in the beginning; and then they will put that knob back with that arrow down this way (indicating). Then when somebody goes to use the machine there is no dial to tell you how much current is going through; and he might turn this and turn it just a fraction of an inch and give you the full load. In view of that possibility, and the importance of protecting human life, we thought it advisable, through a number of experiments, to quickly give them the full load, just as would happen in such a contingency as that. And whenever we did that it invariably killed the animal; except this very tough one we had. And when they got the full load quickly, not as quickly as it would if the knob was not put back in place, getting it very quickly, it died promptly.

Q. You shot the full load to the animal with the pads fastened to them so they could get the direct circuit of the full load?

A. In some cases; not in all.

Q. In all your experiments that you performed with human beings, were simply holding of the pads in the hands and feeling how much tolerance they had?

A. We didn't do any experiments with human beings; just made a few incidental observations.

Q. You didn't actually attempt to use the machine in any way as a therapeutic device to test its effectiveness in any sense?

A. No.

Q. Doctor, when was the matter of your making any experiments with reference to the device first mentioned to you, or brought to your attention?

A. I don't remember the date. It was, I suppose, it was a month or so ago. I don't remember the date, but the representative from the Pure Food and Drug Administration asked me what effect the electric current as given out by such a device that he described would have, and I told him.

Q. Who was that representative; do you recall?

A. I believe it was Mr. Pearson. And I told him what I have told the Court today; but I also told him that I would like to see the device and examine it carefully and work with it, and then he arranged to send it to me.

Q. That has been approximately a month ago?

A. I would say so. I don't remember the exact time.

Q. About how long a time did you take in conducting these experiments?

A. For one experiment?

Q. The total time.

A. I started experimenting from the time I received the instruments and I believe the last experiment was the 14th of January. I didn't experiment every day.

Q. I was meaning approximately how many aggregate hours you put in on the actual experimentation of the machine.

A. I would have to make a guess at that.

Q. That's all right.

A. I would say about seventy hours, or so; between seventy and a hundred hours; maybe a hundred.

Q. When you stated your qualifications in the beginning I perhaps didn't listen too well? You are an M. D.?

A. No, a P. H. D.

Q. You are not a physician?

A. No.

Q. You are a physicist and physiologist?

A. That's right; physiologist.

Q. So you have not practiced medicine or the use of any device, actually, upon a human being in the treatment of disease?

A. That is correct.

Q. Doctor, in May of this year was Dr. Eugene V. Stead, Dean of the Medical School of Emory University?

A. Well, I don't mind trying to answer that question, but in respect to the Court, who would not disregard irrelevant matters—.

Mr. Goodrich:

Answer that.

A. Well, I don't remember the date when Dr. Stead resigned. He was Dean and he resigned sometime during the last year; and then Dr. Hugh Wood was appointed. I don't attempt to remember the dates.

Q. You never discussed these devices at all with Dr. Stead?

A. No, I never mentioned it to him. In fact, I hadn't seen him since I first knew about it.

Q. If Dr. Stead had refused, on behalf of Emory University Medical School, to make tests on this device, and had said that it could not be done without long and slow experiments, and you could not tell by short tests, and did not have the manpower; would you say he was correct?

Mr. Goodrich:
Object to that.

The Court:
Objection sustained.

Mr. Pemberton:
That is all.

(Thereupon, the witness was excused.)

74 DR. ROBERT LEO BENNETT was called as a witness on behalf of the United States, and, being first duly sworn, testified as follows:

Direct Examination.

By Mr. Goodrich:
Q. State your name and address, please.
A. Robert L. Bennett; Warm Springs Foundation, Georgia.
Q. What is your profession?
A. I specialize in physical medicine.
Q. What are the responsibilities of your position at the Warm Springs Foundation?
A. I have charge of all those patients under care for polio who are not undergoing surgery.
Q. Do you limit your practice?

A. I limit my practice to physical medicine.

Q. State, briefly, your educational attainments and your experience since leaving school; with special reference to your training and experience in the field of physical medicine.

A. B. S. and M. D. from the University of Pittsburgh, 1934, 1936; M. S., University of Minnesota, 1940; Fellowship in Physical Medicine, Mayo Foundation, three-year fellowship, First Assistantship in Physical Medicine. I left there and went to the University of Wisconsin as Assistant Professor in Physical Medicine; and in 1941 came down to Warm Springs as Director of the Graduate School and Director of Physical Medicine.

Q. Do you hold any faculty appointments at present?

A. Yes. Professor at Emory University.

Q. What are your hospital affiliations?

A. Warm Springs Foundation Hospital; Emory University Hospital, and Grady Hospital.

Q. Are you a member of any professional or honorary societies in the field of physical medicine?

A. Yes. Member of American Congress of Physical Medicine; American Society of Physical Medicine; Academy of Physical Medicine; and a member of Sigma Si.

Q. Doctor, explain briefly what physical medicine is.

A. A specialty within the field of medicine that deals with the use of physical agents such as heat, massage, exercise, electricity, water, and so on, in the diagnosis and care of diseases.

Q. Is physical medicine an independent branch of medical science, involving different principles and evoking different phenomena from the regular medicine and evoking different reactions in the treatment of disease?

A. No, it is a specialty within recognized medicine; has the same recognized basis.

Q. Would you explain the relationship between physical medicine and general medicine?

A. Well, again, physical medicine is that specialty which uses physical agents, primarily, in diagnosis and care of diseases.

Q. The evidence in this case shows that these devices deliver to the patient a 60 cycle alternating current of pure sinusoidal wave form with a variable voltage, the minimum being zero and the maximum 60, delivered through two moist pad electrodes which are oval in shape and about 3½ inches by 4½ inches in size. Are you familiar with the effects of electric stimulation of that type delivered through such electrodes in the diagnosis and treatment of disease?

A. Yes.

Q. Are there any uses for electric stimulation by such current so delivered in the diagnosis of disease?

A. Not in the diagnosis, unless it might prove in a very negative sort of way that muscle and nerve are intact. You can stimulate muscle with that current.

Q. Are there any uses for electric stimulation by such current in the treatment of disease?

A. There are some little uses; very little. I would never use that type of machine, however, to do the things that this current might be able to do.

Q. What are the limited uses for such electric stimulation?

A. You might be able to maintain partial bulk and weight in apparently normal inertivated muscles at a time when for some reason or other the patient could not voluntarily contract those muscles.

Q. Under what circumstances would that occur, Doctor?

A. I can't think of any particular place that I would use it; but perhaps theoretically it could be used in cases where patients are bedridden for some time and you want to maintain some tone. I don't know of any other reason.

Q. Would you explain as briefly as possible the nature of the disease commonly known as "Infantile Paralysis"?

A. Infantile Paralysis is a disease of the center nervous system. It is caused by a specific germ; it attacks primarily the motor tracts. The name, itself, means a sudden onset of the inflammation in the anterior horns of the spinal cord. However, the disease is not just limited to just that region. It can be found widespread in the entire center nervous system, particularly, the motor area.

Q. What treatments are used in the handling of this disease while it is in its acute stage?

A. In the acute stage it is entirely a medical and nursing problem. The acute stage, insofar as I am concerned, is that stage where the patient is still febrile, still running a fever, and is in danger of developing certain emergencies that would threaten his life.

Q. Now how is that stage treated?

A. By good medical care and nursing, with all emphasis placed on the early recognition of those emergencies about which I spoke that might endanger the patient's life; primarily, rest and watching.

Q. What sequelae does the disease, poliomyelitis, have?

A. It may have the sequelae of weakness, contraction of muscle, periarticular tissue, that is, the tissues around a joint, and may result in actual twisting of the bone.

Q. Is the spine involved in any of these conditions? The sequelae?

A. The vertebrae may be involved.

Q. How are the sequelae dealt with?

A. Primarily, by attempts to eradicate the cause that would increase the sequelae to a point that it might handicap the patient beyond actual weakness. If you are unable to develop power in muscle support, then you might have to add strengthening apparatus, such as braces or a corset.

Q. A part of the labeling of these devices reads as follows: "On July 8th, 1933, a fourteen-year old boy was carried into the Sinuothermic Institute across the shoulders of his Grandfather. He was in a most pitiful condition. His grandmother told Dr. Urbuteit in these words: 'He was just six years old when he was stricken, we called a doctor but we were not satisfied with him so we called another, and another, until we had all the doctors in Buffalo to see him. Dr. Urbuteit, it was a hard blow to see our darling just collapse at his play and never walk again. We have carried him to every doctor and to every institute that has been recommended to us, but all the doctotrs could do was to advise me to continue the treatment which I was personally carrying on as they said, "Nothing can be done for him'. This is eight years now that he has been in this condition; absolutely helpless from his shoulders down. We can't even sit him up as his spine is so limp he just collapses, so we had an iron brace made for him, but it is so heavy and cumbersome he could only stand it on him a short time. Although he was a hopeless case, we never give up hopes and we have heard so much about the wonderful work which you are doing with Sinuothermic we just felt that, Dr. Urbuteit, you might be just the doctor who is going to give our dear grandson back his health'. Dr. Urbuteit examined him with Sinuothermic to locate the cause and then Sinuothermic treatments were applied, and on the tenth day he was able to sit up by himself. His fondest desire was to be able to go to the corner drugstore by himself. Little by little his strength began coming back until he was able to get up on crutches, and then his big moment arrived. He went to the corner drugstore all by himself; from then on he just gained with leaps and bounds and went where he pleased." In your opinion, based upon your training and experience, is there any truth in the representa-

tions that ten days of electrical stimulation by these devices would enable a child with that involvement to sit alone?

A. After eight years of involvement, I have never even heard of anything that approached that.

Q. Are there some reasons why it could not be done?

A. Yes. Because in eight years there is a certain amount of irreversible pathology takes place in muscles and in the vertebral column itself, which would certainly limit that rapid recovery.

Q. Is there an extent of involvement which makes a patient unable to sit alone in poliomyelitis?

A. I have never seen a patient who was paralyzed just from his shoulders down who could then sit up, hyperextend his lumbar so simply. His bones were stuck together by ligaments and that would immediately say there was no possibility of any type of change in ten days.

Q. What would be the indicated therapy for a patient of the type described if he had been received at the Warm Springs Foundation?

A. He would get a complete muscle test; that is, the individual muscles of the spine would be evaluated in terms of actual strength or known resistance. And then we would have placed this patient under routine treatment of muscle re-education where several times a day, every day, our physical therapist would exercise this patient. We usually do that for two months. In other words, give the patient a reasonable share of conservation methods of muscle re-education. If, at the end of that time, we simply did not find any return to muscle strength, then we would resort to some type of strengthening apparatus, such as a brace or corset, to hold him in a safe position so he could continue any activity possible without damage to the spine.

Q. What would be his outlook for the future with that type of treatment?

A. After eight years, and presuming he had fairly good treatment, after eight years the outlook would be very poor.

Q. In your opinion, would he be able to overcome his disabilities of eight years' involvement in a period of ten days, or a period of ten times ten days?

A. Certainly not in ten days, and I greatly doubt ten times ten days.

Q. What is meant by the term, "paralysis"?

A. That is a complete loss voluntarily to contract a muscle.

Q. Are there one or many causes of paralysis?

A. Many.

Q. Does the therapy for each kind of paralysis vary?

A. Yes.

Q. In your opinion based upon your training and experience is the passing of electric current of the type previously described to you by means of the electrodes previously described of any value in the diagnosis of the causes of any type of paralysis?

A. No. It would simply rule out maybe hysteria or malingering.

Q. In your opinion, is electric stimulation with such current through such electrodes of any value in the treatment of paralysis?

A. I would never use it.

Q. Do you believe it would be of any value, in your opinion?

A. No.

Q. The labeling of these devices contains the following representations: "On April 1st, 1924, Dr. Urbuteit left the Isle of Pines aboard a British sailing vessel bound for Tampa, Florida." (Then there was a shipwreck of some kind.) "The day before sailing away from this

British island, the Captain of Ports of Grand Cayman invited Dr. Urbuteit to visit with him. The Captain of Ports told Dr. Urbuteit about his youngest son thus: 'Doctor, my youngest son fell out of the kitchen door when he was two years of age—he is eleven now—there had been no signs of him being injured from the fall for over a year when we noticed that his whole left side stopped growing and now his left arm is totally paralyzed and his left foot is so twisted that he walks on his ankle instead of the sole of his foot and the one side of his face is smaller, in fact his whole left side is smaller by several years of growth. Do you suppose there is a doctor in the United States that could help my son? The doctor here said that the boy has a clot on his brain and in order to make him well he would have to have a piece cut out of his skull'. Dr. Urbuteit asked to see the boy. When the boy was ushered in Dr. Urbuteit made a careful examination and found the cause which could be remedied without an operation, so Dr. Urbuteit spent the rest of the day teaching the father how to cure his own son. It was not until nine years alter that Dr. Urbuteit had direct word as to the results of that afternoon in Grand Cayman. A brother of the afflicted boy called upon Dr. Urbuteit, in Tampa, he was sent by his father to show his gratitude. The brother said 'My youngest brother is now around six feet tall and is a perfect specimen of manhood, thanks to you Dr. Urbuteit'." In your opinion, based upon your training and experience, will such electric stimulation through such electrodes overcome the atrophy of disuse of some nine years in the manner described in the labeling quoted to you?

Mr. Pemberton:

I don't wish to object, but I think if counsel will read the thing a little bit more carefully he will find no ref-

erence to a sinuothermic machine, whatever. As a matter of fact, it was not involved whatsoever.

The Court:

Objection overruled.

A. I can't possibly see how the use of that apparatus could in any way effect that.

Q. Is there more than one kind of arthritis?

A. Yes, several.

Q. What are some of the different kinds, without attempting to exhaust the list.

A. We usually classify it into six rather large groups. The first is the specific type, where the arthritis is due to a known germ. The second is the rheumatoid type. The third type is the degenerative type; sometimes called senescent or hypotrophic arthritis. The fourth kind is the gouty arthritis, due definitely to diseased gout. The fifth kind is the neoplastic, where it is due to new growth, tumor growths. Then, finally, there is a classification of mixed types, which usually include the combination of rhumatoid and degenerative.

Q. Does the current of the type described to you, delivered through the electrodes described to you, have any value in the treatment of any type of arthritis?

A. No.

Q. Is it useful in arthritis due to infection with the gonococcus?

A. No.

Q. Why not?

A. It has no effect on the gonococcus whatsoever.

Q. Is there any use of it in arthritis due to gout?

A. No, it is dangerous.

Q. Why?

A. Because any type of mobilization definitely makes it worse.

Q. Based upon your training and experience would the use of electric current as electric stimulation of the kind described to you be of any value in the diagnosis, treatment or cure of the following diseases: Painful breathing?

A. No.

Q. Internal growths?

A. No.

Q. Hardening of the arteries?

A. No.

Q. Heart disease?

A. No.

Q. Cancer.

A. No.

Q. Tuberculosis?

A. No.

Q. Deficient hearing?

A. No.

Q. Hay fever?

A. No.

Q. Glandular disorders?

A. No.

Q. Tumors of the bladder?

A. No.

Q. Uterine hemorrhage?

A. No.

Q. Diseased kidneys?

A. No.

Q. Peritonitis?

A. No.

Q. Low blood pressure?

A. It might temporarily increase that blood pressure.

Q. Ulcerated colon?

A. No.

Q. Appendicitis?

A. No.

Q. Obstructed colon?

A. No.

Q. Menstrual dysfunction?

A. No.

Q. Do the opinions you express represent not only your personal opinion, but also the consensus of well informed medical opinion?

A. Yes.

Mr. Goodrich:

That is all.

Cross Examination.

By Mr. Pemberton:

Q. Do you use electric therapeutic devices in your practice?

A. Yes.

Q. Which ones do you use?

A. Galvanic current faradic current; also use a machine for the determination of chronaxia.

Q. What do you use that galvanic and faradic current for?

A. We use that for diagnosis of perforan nerve injuries. We also use the galvanic current for iontophoresis, which is a means of transferring ions into the skin. We use our faradic current occasionally to teach an individual how to use a specific muscle. It has a very limited use there. We may further use it to determine hysteria or to overcome a psychoneurosis; it is really psychotherapy. We also use the ordinary type of diathermy.

Q. You have never used the device that is involved in this litigation?

A. Yes. I have experimented with all types. We used the 60 cylcle current as indicated by counsel here.

Q. You have not used one of the specific devices manufactured by Dr. Urbuteit?

A. No, I have never seen it.

Q. And you have no actual experience, either in direct experience or observation of that device?

A. No.

Q. You spoke a moment ago about infantile paralysis being caused by a germ. Has the infantile paralysis or poliomyelitis germ ever been isolated?

A. It has not only been isolated, but has now been seen.

Q. The treatment for polio has varied as time went on; has it not? I mean it has been changed by the medical profession as to what the proper treatment would be?

A. The amazing thing, as we have recently reviewed all that, the over-all plan has not changed one bit. We have gone into a lot of discussion of ways of doing things better within that over-all routine; but the amazing thing is that it has not changed; but we have gotten into some discussions about actual technique.

Mr. Pemberton:

That is all.

(Thereupon, the witness is excused.)

DR. H. KINGSBURG was called as a witness on behalf of the United States and testified as follows:

88 Direct Examination.

By Mr. Goodrich:

Q. State your name and address.

A. H. Kingsbury; 401 Richmond Avenue, Orlando, Florida.

Q. What is your profession?

A. I am a doctor of medicine

Q. Are you engaged in any capacity at the Florida State Tuberculosis Sanitarium in Orlando?

A. I am a physician and surgeon; a member of the staff of the Florida State Tuberculosis Sanitarium.

Q. How long have you been engaged in the diagnosis and treatment of tuberculosis?

A. I have been engaged in the diagnosis and treatment of tuberculosis for a period of ten years.

Q. Will you state briefly your educational attainments and your experience in the field of tuberculois?

A. I am a graduate of Wisconsin University with a B. S. Degree; and graduate of the University of Louisville Medical School with the degree of medicine. I completed an interneship at Madison General Hospital, Madison Wisconsin; a Junior Residency at Waverly Hills Tuberculosis Sanitarium; in 1936 I was the Senior Resident Physician at the Wisconsin State Sanitarium.

Q. Is that a tuberculosis sanitarium

A. It is; at Wales, Wisconsin; I was there until October, 1937. I then came to Florida and was Chief of the Resident Staff at the Florida State Tuberculosis Sanitarium until February of 1942. I was a member of the staff then at Fitzsimmons General Hospital in Denver, Colorado, in the armed services, from February, 1942 until September of 1944. I was Chief Thoracic Surgeon at the Burns General Hospital in Santa Fe, New Mexico until discharged from the Service in March of 1946.

Q. Would you explain, briefly, the nature of the disease tuberculosis?

A. Tuberculosis is a specific disease caused by the tubercle bacillus and is characterized by a lesion known as the tubercle formation within the tissues of the infected body. These tubercles have specific characteristics which are identifiable by microscoping of the tissues.

The identification or diagnosis of the disease depends finally upon the recognition of the organism infecting the tissues and reproduction of the disease in an experimental animal.

Q. Will you describe briefly the nature of pulmonary tuberculosis, with just whatever reservations may be necessary from your general description?

A. Pulmonary tuberculosis is an inflammation of the lungs, specifically by organisms which gain access to the body by various means of exposure to someone else who has the disease.

Q. How is the disease pulmonary tuberculosis diagnosed?

A. The disease is diagnosed by means of X-ray examination of the individual and, of course, finally upon recovery of the organism and sputum examinations. Positive identification depends on reproduction of a similar lesion in an experimental animal.

Q. Is electro-diagnosis used to any extent in the diagnosis of pulmonary tuberculosis?

A. Electro-diagnosis in the sense that you use X-ray as an aid to diagnosis.

Q. Any other electrical device beside X-ray?

A. Not so far as I know.

Q. What is the treatment for pulmonary tuberculosis?

A. The treatment for pulmonary tuberculosis is based upon certain principles; one augments the ability of the individual to overcome his own disease, either by obtaining rest for the individual, rest for the localized part.

Q. By that you mean rest for the lung?

A. Rest for the lung, itself; and, of course, augmenting his own resistance.

Q. Is the expulsion of fluid from the lungs in itself an adequate treatment of pulmonary tuberculosis?

A. I should say that the expulsion of fluid from the lungs is in itself not considered a treatment for tubercu-

losis. Certainly not an adequate treatment, because it does not depend on these principles which we apply to the treatment of tuberculosis. In other words, augmenting the expulsion of fluid or pus from the lung is in itself not a complete treatment. In other words, it would be treatment of symptoms rather than the disease process.

Q. Does pulmonary tuberculosis affect the nerves that control coughing?

A. The process of pulmonary tuberculosis sets up by-products which irritate the bronchials and nerve endings in the bronchials thereby stimulating cough to express the debris from the lung.

Q. Would the electrical stimulation of the muscles in the chest wall result in the expulsion of fluid from the lungs?

A. The expulsion of fluid from the lung is a complicated process, which involves a great many nerves and a great many pathways of reflex and voluntary recording in the brain in order to produce a cough to expel material from the lung. Stimulation of one or more individual nerves would not produce a cough. It might augment a cough which the patient himself might be encouraged to produce; but certainly the contraction of the muscles of the chest wall in itself would not produce expulsion of fluid or pus from the lung.

Q. The evidence in this case shows that the devices involved deliver to the patient electrical current which is identical as that coming from the ordinary wall socket of a house, alternating current, with the exception that the voltage is stepped down to a maximum of 60 volts and a minimum of zero, this current being delivered to the patient by means of two moist pads which are oval-shaped electrodes approximately 3½ inches by 4½ inches in size. Are there any uses of electric stimulation by such current so delivered to the patient in the diagnosis,

cure, mitigation, treatment or prevention of pulmonary tuberculosis?

A. To the best of my knowledge and experience and from following literature I know of no specific benefit obtainable from such stimulation.

Q. Would it have any such value for the treatment of any other type of tuberculosis?

A. I should say certainly that it does not follow the accepted principles of treatment of tuberculosis infection of any kind.

Q. Is muscular stimulation of the chest wall of value or a disadvantage in the treatment of pulmonary tuberculosis?

A. I should say that it is difficult to state categorically that it would be of benefit or of harm to an individual affected with pulmonary tuberculosis. It certainly has not appeared as a true and accepted method of treating tuberculosis in the literature of the English speaking world.

Q. The labeling of these devices includes the following representations: "What can be done for tuberculosis in the last stages. There is a cure for tuberculosis if it is caught in time and the proper care and treatment is given to the sufferer. But what chance has a poor unfortunate who is in the last stages? Early in February, 1929, a sweet silver haired old lady came to the Sinuothermic Institute for treatments for her hearing, as she was quite deaf; she responded so rapidly she was amazed after having been treated by specialists for years without receiving one bit of help. One day this kindly old lady said to Dr. Urbuteit, 'Doctor, this Sinuothermic is so wonderful I believe it will cure tuberculosis. I have a stepson who has been given about three months to live, the doctors said that he would pass out about in May or even April, so you see he is in a very bad condition; they sent him home from the sanitarium so he could

be home during his last days, so we brought him to Florida thinking that it would be better for him in this mild climate, but we have to leave here by the first of April. I have already told him about these treatments, but he knows that nothing can be done for him, but I did get him to promise to come with me tomorrow so he could meet you, and doctor when I get him here, do what you can to get him to submit to a Sinuothermic examination.' The next morning, on February 14, 1929, this dying man came with his step-mother; he could not stand the indoor air so Dr. Urbuteit made him comfortable on the side veranda where he could carry on conversation with his stepmother and still be in the out of doors air. It took a lot of persuasion before he consented to an examination. Dr. Urbuteit did not stop with the examination. After locating the few nerves which still functioned, Dr. Urbuteit proceeded to empty the lungs. It took about thirty minutes; the amount of pus which Sinuothermic brought up is unbelievable. He was allowed to rest after the treatment but when he did get up he was full of a desire to live again, so every day from then on until the first of April he never missed a treatment." And he went on and went from the grave to the pulpit. In your opinion based upon your training and experience, could the lungs be emptied in the manner described?

A. I should say certainly the lungs could not be emptied in the manner described; certainly not of the disease process itself.

Q. Even if fluid could be expelled would you consider the man cured?

A. I certainly would not consider the man cured without further evidence. In other words, we do not speak of individuals with pulmonary tuberculosis disease as ever becoming cured, they become cases of arrested tuberculosis after a careful evaluation of their symptoms. Once afflicted with pulmonary tuberculosis, always a

tuberculous individual, never cured. They may live with their disease their normal expectancy, but they are never, so to speak, cured.

Q. It is further stated in this labeling that the final examination was in 1935, at which time specimens were sent to the Florida State Laboratory and the report was returned marked tubercular bacilli were not found. What is the significance of one negative sputum examination in determining the cure for tuberculosis?

A. I would say one negative sputum would have no significance whatsoever in determining the disease process.

Q. At the Florida State Sanitarium for tuberculosis how many sputum tests are made before an arrested case is found?

A. Well, a patient under our care at the Florida State Sanitarium must remain negative under repeated examinations of at least monthly intervals for a period of six months under specified conditions of exercise and activity without the manifestations of symptom, or any of X-ray, or lesions in the lungs, in order to be called an arrested case and to be allowed the hazards of his own home activities.

Q. What is the prognosis or the outlook for a patient with far advanced tuberculosis?

A. Of course, the outlook for any individual with pulmonary tuberculosis is difficult to predict, but a far advanced case certainly is gravely ill and to the best of my knowledge and experience could not be pronounced arrested or continue with his normal activities without very careful study over a long period of time, and an individual with far advanced disease is not necessarily a hopeless case. In other words, one cannot tell what the outcome will be until a period of careful observation and careful rest and therapy is carried on, so that one cannot predict to any great degree the time a person will live.

Q. What is the purpose of collapse therapy, collapsing the lung in the treatment of pulmonary tuberculosis?

A. The principle of collapse therapy is merely to apply the basic principle of rest to the individual and to the local part affected.

Q. Would the agitation of the local part by some electrical stimulation be contraindicated in that condition?

A. I should say that any increase in activity of the local part would be contraindicated. Certainly not unless applied as a test of that individual's tolerance to find out whether or not he might be able to be rehabilitated and allowed to go about his ordinary occupation.

Q. Is the symptom painful breathing sometimes caused by infection with the tubercle bacillus?

Q.[A.] Painful breathing is a matter of the infection of the pleural surface of the lung with the tubercle bacillus. This painful breathing is known as pleurisy and is a common symptom in the disease.

Q. Would the current delivered by this machine in the manner I have described be of any value in relieving such painful breathing?

A. To the best of my knowledge I can see no way in which it would relieve the painful breathing.

Q. Doctor, do the opinions which you have expressed here represent not only your personal opinion but also the consensus of well considered medical opinion as you have encountered it?

A. I should say with association with other members engaged in the practice of the specialty of the treatment of tuberculosis and from following the literature over this period of years, the opinions which I have expressed are in general the opinions of the profession as a whole.

Q. Do you have an opinion upon the public health dangers of the home use of such electrical stimulation in the treatment of pulmonary tuberculosis?

A. Of course, our efforts are not alone aimed at the rehabilitation of individuals, we are concerned with the spread of the disease throughout the population in general; and therefore my own opinion would be that the usage of such appliances would be detrimental to the prevention and spread of the disease in that individuals so afflicted might be mislead and would therefore not avail themselves of isolation from the general public when they are in the infectious stages of the disease.

Cross Examination.

By Mr. Pemberton:

Q. You have not used the treating machine that is under discussion in this trial; have you?

A. I have not.

Q. And you do not use electrical therapy to any extent at all in your practice?

A. Not in the sense that it is used here. We use electrical devices as aids in diagnosing and in the surgical treatment of tuberculosis, but not as a stimulation of the body.

Q. You have not made extensive experimentation in the electrical field?

A. We have not, because we practice in the province of already accepted methods and therefore do not do experimental therapy upon patients.

Q. Then you are not familiar with this device at all?

A. I have never seen it until I entered the Courtroom today.

Mr. Pemberton:

That is all.

(Thereupon, the witness was excused.)

Thereupon, DR. J. MAXCEY DELL was called as a witness on behalf of the United States and, being first duly sworn, testified as follows:

98 Direct Examination.

By Mr. Goodrich:

Q. Give your name and address for the record.

A. James Maxcey Dell, Jr.; 333 West Main Street South, Gainesville, Florida.

Q. What is your profession?

A. Roentgenologist.

Q. Do you limit your practice to roentgenology?

A. I do.

Q. What are your qualifications with reference to roentgenology?

A. I am a member of the American Board of Radiology.

Q. Any others?

A. I served as Chief of the Department of Roentgenology at Batty General Hospital, Rome, Georgia, for two years.

Q. When were you licensed to practice medicine?

A. 1931.

Q. Are you a member of any professional societies?

A. Yes.

Q. Would you name a few of them?

A. I am a member of the American College of Radiology; Radiologist Society of North America; Florida Radiologists; American Medical Association; Florida Medical Association; and Alachua County Medical Association.

Q. Do you hold any special offices?

A. President-elect of the Alachua County Medical Association; Secretary and Treasurer of the Florida Radiological Society.

Q. What is the specialty of Roentgenology?

A. It deals with the diagnosis and treatment of disease by X-ray.

Q. How is the X-ray used in the diagnosis of disease?

A. It is used by passing a ray through the body which precipitates silver salts on an emulsion covered celluloid base producing shadows of various densities.

Q. From those shadows are you able to diagnose the internal conditions reflected by such shadows?

A. With a high degree of accuracy.

Q. Doctor, is there any one diagnostic device which you are familiar with which may be used to the exclusion of all other d'agnostic devices or methods and which is "never failing" and which will record the cause of any disease whatsoever?

A. No.

Q. What are the limitations upon X-ray in the diagnosis of cancer?

A. Its inability to detect a very early growth, and at times to differentiate a cancer from an inflammatory process.

Q. What is essential to the absolute diagnosis of cancer growth?

A. Microscopic confirmation on examining tissue from the lesion.

Q. What is that known as, medically?

A. Biopsy.

Q. Is X-ray used in the treatment of cancer?

A. It is.

Q. How is it used?

A. By directing X-rays to the lesion.

Q. Do you deliver a measured dose of X-ray in the treatment of cancer?

A. We do.

Q. What is the effect of X-ray in cancer therapy?

A. X-ray destroys the cancer cells.

Q. Does X-ray destroy the normal cells which are in the vicinity of the cancerous growth?

A. If properly applied it does not.

Q. Are surgery, X-ray and radium treatment contra-indicated in the treatment of cancer?

A. They are not.

Q. The evidence in this case shows that the devices deliver to the patient a current identical in form with that of an ordinary electric light current except that the voltage has been stepped down. This current is delivered through two moist pad electrodes which are oval in shape and approximately 3½ by 4½ inches in size. Is that current comparable in any way to X-ray?

A. It is not.

Q. I was speaking of the sinuothermic machine when I gave you the hypothetical question.

A. Yes.

Q. In your opinion, based upon your training and experience, would such a current delivered in the manner described have any therapeutic value at all in the treatment of cancer?

A. None that I know of.

Q. What are the therapeutic limitations of X-ray in the treatment of cancer?

A. Its inability, or our inability, to deliver a sufficient doese to lesions located at a depth, and the fact that certains tumors are radio resistant.

Q. Are the effects of X-ray treatment in cancer immediately observable?

A. By "immediately", do you mean in a few minutes or a few hours?

A. [Q.] Yes. How long a time normally passes, or what time might be expected to pass, before any evidence of the destruction of the cancerous growth would be forthcoming?

A. Taking the most radio responsive tumor and the largest safe dose, no sooner than one week.

Q. And for the most resistive type of neoplastic cell?

A. It may be delayed as long as two or three weeks.

Q. In your opinion, based upon your training and experience, does radiation treatment of cancer alter the basic functions of the body as a whole so as to make it incapable of response to other types of therapy?

A. If properly administered, no.

Q. Would X-ray treatment of a cancer make it incapable of response to electrical stimulation treatment, assuming that such electrical stimulation might have some considerable value?

A. In the first place, I can't conceive of it having any value; and knowing the physical properties of the electrical current I don't see how the question can be answered.

Q. Would the type of electric current delivered in the manner described to you have any value in the diagnosis, treatment, cure, mitigation or prevention of benign tumors of the bladder or uterus?

A. The best medical evidence in the country would say "No" to that question.

Q. Does the medical profession know of any way to deal with cancer other than X-ray radium or surgery?

A. Not successfully.

Q. Doctor, do the opinions which you have expressed represent not only your personal opinions, but the consensus of well considered medical opinion?

A. They do.

Cross Examination.

By Mr. Pemberton:

Q. Have you used at all the device described here as the sinuothermic machine?

A. I have not.

Q. You are not familiar with it?

A. I am not; except from the description given.

Q. Doctor, in amplification of the testimony you gave a moment ago about what shows up on the X-ray and how it can be read, will you look at this—

Mr. Goodrich:

Object to the introduction of these X-rays without some predicate being laid for them.

The Court:

Objection sustained.

Mr. Pemberton:

I am asking him what the nature of that X-ray is, what it indicates. He testified a moment ago as to how X-ray showed up, what it did as to lights and shadows.

The Court:

All right, let him answer.

A. In the first place, this is a film of a barium-filled colon on some opaque medium. The study of the colon without flouroscopy is most of the time of very little value. The present film shows the shadows of the rectum and sigmoid colon obscuring each other and in this present film no definitely abnormality is noted, although the right half of the colon is incompletely filled.

Q. Does that indicate anything about the disease, or can you tell?

Mr. Goodrich:

Object to that.

The Court:

Objection sustained.

Mr. Pemberton:
No further questions.

(Thereupon, the witness was excused.)

DR. W. C. THOMAS was called as a witness on behalf of the United States, and, being first duly sworn, testified as follows:

104 Direct Examination.

By Mr. Goodrich:
Q. State your name and address.
A. W. C. Thomas; Gainesville, Florida.
Q. What is your profession?
A. Physician.
Q. When were you licensed as a physician?
A. 1923.
Q. Where did you obtain your medical degree?
A. Johns Hopkins.
Q. Did you receive any special training after that in the armed forces?
A. I was in the armed forces for about seven and a half years.
Q. Do you belong to any professional societies?
A. Yes.
Q. Would you give the names of a few?
A. Alachua County Medical Society; Florida Medical Society; Southern Medical Association; American Medical Association.
Q. What are your hospital affiliations?
A. I am on the staff of the Alachua County Hospital.
Q. Do you teach any subjects over there to the nurses?
A. Yes.

Q. Do you hold any special office in any of those associations?

A. I am president-elect of the Florida Medical Society.

Q. Do you restrict your practice to anything specific?

A. Not absolutely.

Q. Do you particularly engage in any particular lines?

A. Yes.

Q. What is that?

A. Obstetrics.

Q. The testimony in this case shows that the current delivered by these sinuothermic machines is identical in form with that delivered from an ordinary wall socket alternating current, with the exception that the voltage is stepped down, the minimum being zero and the maximum being 60. The current is delivered to the patient through two moist pad electrodes approximately 3½ inches by 4½ inches in size, the electrodes being applied to the area of the pain. What effect would that current have on the body?

A. Do you mean temporary or permanent?

Q. Temporary, or permanent.

A. It may give a feeling of warmth. You can get a feeling of shock. As far as permanent, it will have no permanent effect.

Q. Based upon your training and experience would a current of that description delivered in the manner described, have any effect in the diagnosis, treatment, mitigation, prevention or cure of deficient hearing?

A. No.

Q. Would it have any useful effect in the diagnosis, treatment, mitigation, prevention or cure of any menstrual discomfort or dysfunction associated with menstruation?

A. No.

Q. Would such a current, in your opinion, delivered in the manner described, have any use in the diagnosis, treatment, mitigation, prevention or cure of prostate trouble?

A. No.

Q. In your opinion based on your training and experience would such a current delivered to the patient in the manner described be useful in the diagnosis, treatment, mitigation, prevention or cure of tumors of the uterus?

A. No.

Q. Does the term tumors include cancer?

A. It may include cancer.

Q. The labeling of these devices reads, in part: "Early in February of 1934, several people from Rhode Island were being treated at the Sinuothermic Institute. One day they brought a friend, who was just passing through. This friend was so impressed she asked for a private consultation with Dr. Urbuteit. She said, 'Doctor, my daughter is dying from an internal cancer, she has been operated upon twice; both major operations; the first operation they removed all of her female organs; after that she felt fairly good for a short time but then the cancer spread all through her; the next operation they moved the outlet of the stomach from the duodenum to the pit of the stomach; now she is hemorrhaging so bad the doctors said it is only a question of time; when I asked how much time he said that she will never see another Christmas. Do you think at this late stage that you would save my daughter's life, with Sinuothermic treatments?' 'It sounds like she is very low,' Dr. Urbuteit said, 'but where there is life there is hope; of course, I cannot promise you anything but if we do not try then we cannot expect anything.' On February 23rd, 1934, this poor sick emaciated little mother of two fine sons arrived at the Sinuothermic Institute for treatments.

She was in a lamentable condition, it was a miracle how she hung onto life; as she was hemorrhaging so badly and her eyes were sunken and black half way down her face; she was so terribly sick one would wonder what kept her alive. It took nearly five weeks to subside the hemorrhaging but after that she just picked up with leaps and bounds, she gained weight fast and in just a couple of months she was going out by herself and by the middle of June she was able to travel so she went back home. She purchased her own Sinuothermic machine and treated herself thereafter. She visited the Sinuothermic Institute recently and a more gorgeous looking woman than she is right now would be difficult to find, she is the picture of health and beautiful. Although she should continue her treatments, as far as she is concerned she is cured of one of the worst cases of internal cancer which is possible to have." In your opinion based upon your training and experience, is it possible that this woman was cured of one of the worst cases of internal cancer?

A. She didn't have cancer.

Q. If a patient with a cancer of the uterus received only this curent as treatment, what would happen to her?

A. It would not have any effect at all on her.

Q. What would happen to the cancer of the uterus?

A. It would advance.

Q. As it advances does the possibility of cure lessen?

A. Yes.

Q. And why is that so?

A. Because it spreads beyond the immediate locality of the cancer. It may spread to other organs and as long as it is in exsitence the more apt it is to spread.

Q. Is it a characteristic of cancer that it is a growing thing rather than a quiescent?

A. It is, definitely. It varies in the growth; in older people grows slowly, and younger people more rapidly.

Q. You say the growth of the cancer involves the other organs if left without proper treatment?

A. Yes.

Q. The labeling of these devices also contains the following representation: "On November 20, 1931 a husband and wife entered the Sinuothermic Institute for a consultation with Dr. Urbuteit and here is their story as told by the husband. * * * Dr. Urbuteit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but that she was also pregnant about five months. * * * On the fifth day she began discharging the contents of the tumor until it had completely drained and the fetus began to develop. * * * 'There is no previous case on record', said Dr. Urbuteit, 'where a large fibroidal tumor was removed from within the uterus without causing a miscarriage'." Is there any electrical current which will cause a fibroid tumor of the uterus to drain and disappear, in your opinion?

A. No.

Q. Is it possible to remove a fibroid from a pregnant uterus by surgery?

A. Yes.

Q. In your opinion based on your training and experience would such a current delivered to the patient in the manner described be useful in the diagnosis, treatment, mitigation, prevention or cure of uterine hemorrhage?

A. No.

Q. Is it possible for a person to have a ninety-three percent developed cancer of the whole abdomen and continue to live?

A. No. But you cannot determine when a cancer involves 93% of the whole abdomen.

Q. If it did involve that much, would the woman be dead long since?

A. Yes.

Q. Is there any one diagnostic device if when used to the exclusion of all other methods is absolutely "never failing" and will register exactly the cause of each disease?

A. No.

Q. In your opinion, based upon your training and experience, would the current described to you have any value in the diagnosis, cure, mitigation or treatment or prevention of painful breathing?

A. No.

Q. The same question for hardening of the arteries?

A. No.

Q. The same question for heart disease?

A. No.

Q. Paralysis?

A. No.

Q. Diabetes?

A. No.

Q. Tuberculosis?

A. No.

Q. Hay fever?

A. No.

Q. Glandular and nervous disorders?

A. No.

Q. Diseased kidneys?

A. No.

Q. Nervousness?

A. No.

Q. Low blood pressure?

A. No.

Q. Ulcerated colon?

A. No.

Cross Examination.

By Mr. Pemberton:

Q. What electrical therapeutic devices, if any, do you use in your practice?

A. None but the cardiograph.

Q. Have you ever used the device here referred to as Sinuothermic device?

A. No.

Q. You have had no experience with it whatever?

A. No.

Mr. Pemberton:

That's all.

Re-Direct Examination.

By Mr. Goodrich.

Q. Can you say upon the basis of your experience and knowledge of the functions of the body and what makes it work both in condition of health and disease, that treatments of this kind would have no value?

A. That would be my opinion.

Mr. Goodrich:

That's all.

(Thereupon, the witness was excused.)

DR. JOHN E. MAINES was called as a witness on behalf of the United States, and, being first duly sworn, testified as follows:

112 Direct Examination.

By Mr. Goodrich:

Q. State your name for the record.

A. John E. Maines, Jr.

Q. What is your address?
A. 1207 W. Boulevard, Gainesville, Florida.
Q. What is your profession?
A. Physician.
Q. You also do surgery?
A. Yes, I do.
Q. When did you obtain your license?
A. 1926.
Q. Where did you obtain your medical degree?
A. Tulane University School of Medicine.
Q. Have you had any special training since leaving school in medical subjects?
A. Yes.
Q. On what subjects?
A. On Surgery, and I would say Gynecology.
Q. Do you hold any society memberships in professional medical societies?
A. Yes. The County society here, Alachua County Medical Society; Florida State Medical Society; and American Medical Association.
Q. What are your hospital affiliations?
A. Alachua County Hospital.
Q. Do you hold any official position at that hospital?
A. Chief of Staff.
Q. Do you instruct in any courses over at the hospital?
A. Yes.
Q. What do you teach, and whom?
A. I teach Gynecology to the nurses.
Q. Do you restrict your practice in any way, or are you a general practitioner?
A. I am a general practitioner; partially restricted.
Q. What do you mean by that?
A. I mean the majority of my work consists of surgery.

Q. As a surgeon, have you treated the following conditions or diseases: Appendicitis?

A. Yes.

Q. Cancer?

A. Yes.

Q. Internal growth?

A. Yes.

Q. Obstructed colon?

A. Yes.

Q. Peritonitis?

A. Yes.

Q. Tumor of the bladder and uterus?

A. Yes.

Q. The evidence presented in this case shows that the sinuothermic machines you see in front of you deliver to the patient a current which is identical in form with that delivered from an ordinary electric light socket, the exception being that the voltage of that current is reduced. It is delivered to the patient through two moist pad oval-shaped electrodes, they being approximately 3½ inches by 4½ inches in size. In your opinion, based upon your training and experience, would such a current delivered to the patient in the manner described be useful in the diagnosis, treatment, mitigation, prevention or cure of appendicitis?

A. No.

Q. What is the treatment for acute appendicitis?

A. Surgery.

Q. If a patient with an acute appendicitis received only this current as treatment, what would happen to him?

A. There wouldn't anything happen; he wouldn't get any better.

Q. Are there any possible complications which would develop?

A. The patient would probably get worse because he was not receiving proper treatment.

Q. Is there possibility of rupture of the appendix as a following sequela?

A. Yes.

Q. What are those sequela?

A. Usually it would be peritonitis.

Q. Is peritonitis a dangerous condition?

A. Very dangerous.

Q. In your opinion, based upon your training and experience, would a current of the type described to you delivered in the manner described to you, be useful in the diagnosis, treatment, mitigation, prevention or cure of cancer?

A. No.

Q. How is cancer dealt with in the practice of medicine?

A. Cancer is dealt with by surgery or radiation therapy.

Q. By radiation therapy you include radium and X-ray?

A. That is correct.

Q. Would a current of the type described to you, delivered in the manner described be usfeul in the diagnosis, treatment, mitigation, prevention or cure of an internal growth?

A. No.

Q. The same question for obstructed colon?

A. No.

Q. What is the treatment for obstructed colon?

A. Surgery.

Q. Is there any other way to deal with it?

A. Comparatively speaking, it is possible that you might aid in some type of palliative therapy.

Q. Is it possible to remove obstruction of the colon in a child by some physical measure?

A. No.

Q. In your opinion, would the current of the type described delivered in the manner described be of any value in the diagnosis, treatment, mitigation, prevention or cure of peritonitis?

A. No.

Q. If a person had a generalized peritonitis following the rupture of an inflamed appendix and received only this current as the treatment what would be the outcome of the disease?

A. The patient would steadily get worse.

Q. In your opinion, based upon your training and experience, would the current of the type described to you delivered in the manner described be of any use in the diagnosis, treatment, mitigation, prevention or cure of tumors of the bladder and uterus?

A. No.

Q. Does surgical treatment so alter the basic functions of the body as a whole so as to make it incapable of response to other therapy?

A. No.

Q. Is there any one diagnostic device which when used to the exclusion of all other diagnostic devices is "never failing" and registers the exact cause of every diseased condition?

A. No.

Q. The labeling of these devices reads in part as follows: "During the treatments of my colon indescribable, odorus specimens or growths of unusual appearances, containing pus and blood, were continuously passed. I averaged passing a quart of pus and pus formations daily for several months." In your opinion, is it possible for the human body to form a quart of pus daily for several months?

A. No.

Mr. Goodrich:
That is all.

Cross Examination.

By Mr. Pemberton:
Q. Are you familiar with the sinuothermic machine involved in this litigation?
A. Yes.
Q. To what extent are you familiar with it?
A. I understand the voltage.
Q. You mean from the testimony that was given?
A. Yes.
Q. You have never used it?
A. No.
Q. You don't know anything about its actual usage and experience gained from its use?
A. No, I don't know anything about the machine, only the test mony given here.

Mr. Pemberton:
That's all.

Re-Direct Examination.

By Mr. Goodrich:
Q. Is this a machine of the type used and recognized by the medical profession?
A. No.

(Thereupon, the witness was excused.)

Mr. Goodrich:
This completes the witnesses we have available at this time. We have another witness we can put on in the morning.

The Court:

Take a recess until 10 o'clock tomorrow.

(Thereupon, on Friday, January 24, 1947, at 10 o'clock in the forenoon, Court reconvened and the following proceedings were had:)

DR. J. WEBSTER MERRITT was called as a witness on behalf of the United States, and, being first duly sworn, testified as follows:

118 Direct Examination.

By Mr. Goodrich:

Q. Will you state your name and address for the record?

A. J. Webster Merritt; 2033 Riverside Avenue, Jacksonville, Florida.

Q. What is your occupation or profession?

A. Physician.

Q. When were you licensed to practice medicine?

A. In 1935.

Q. What is your educational background?

A. I was graduated from the University of Florida with a Pharmacist's Degree in 1927; B. S. Degree in 1929 from the Johns Hopkins School of Medicine; M. D. in 1933; and I was trained on the Harvard Medical Service, Boston, 1933 to 1935.

Q. Are you a member of any professional or honorary societies?

A. Yes.

Q. Name a few for the record.

A. Duval County Medical Society; Florida Medical Association; Southern Medical Association; American Medical Association; American College of Physicians.

Q. Do you hold any faculty appointments or teach physicians at the present time?

A. Yes.

Q. Will you state what they are, briefly?

A. Associate in Medicine on the Duval County Medical Staff, Duval County Hospital, Jacksonville, Florida; and Head of the Department of Cardiovascular Diseases of Duval County Hospital; Instructor of Nurses at Riverside Hospital.

Q. Do you hold any special offices or special diplomas of any kind?

A. I am a member of the American College of Physicians and a Diplomate of the National Board of Medical Examiners, and American Board of Internal Medicine.

Q. How does one become a Diplomate?

A. By taking special examinations. The National Board of Medical Examiners requires that you be a graduate of a Grade "A" medical school and that you take the examination in three parts. The American Board of Internal Medicine requires you to have five years of special training in your specialty before you are allowed to take the examination.

Q. Have you made any contributions to the medical literature?

A. Yes.

Q. What subjects were principally dealt with?

A. Heart diseases, thyroid diseases, diseases of the lung and diseases of the circualtion.

Q. Do you specialize in any particular branch of medicine?

A. Internal Medicine.

Q. What is internal medicine?

A. It deals with the study of the disease of organs and the tissues which lie within the body.

Q. As a specialist in internal medicine, do you deal with the following diseases and conditions: Painful

breathing, Arthritis, Hardening of the Arteries, Heart Disease, Paralysis, Diabetes, Tuberculosis, Hay Fever, Glandular and Nervous Disorders, Diseased Kidneys, Nervousness, Nerve Disorders, Low Blood Pressure, Ulcerated Colon?

A. Yes.

Q. What is necessary in the diagnosis of these various conditions?

A. It is necessary to take a careful history, perform a physical examination and then any clinical studies such as X-ray examination, examination of the blood and sputum, and so forth.

Q. Are all of these which I have listed treated in the same way?

A. No.

Q. Doctor, the evidence presented in this case with regard to the device called sinuothermic, which you see in front of you, is that they deliver to the human patient a current which is identical with that delivered from an ordinary wall socket alternating current, the difference being the voltage of that current is stepped down to a variable value, variables between zero and 60, which is applied to the body through two moist pad electrodes, approximately 3½ inches by 4½ inches in size, and oval in shape. Does a current of this type delivered to the patient by placing such electrodes upon the body have any use in the diagnosis, treatment, mitigation, prevention or cure of the symptom of painful breathing?

A. No.

Q. Could you state whether or not there exists a nerve trouble which interferes with the free action of the diaphragm, which also causes stabbing pain through the chest upon breathing and causes a cramp which may occur on and off for three years?

A. No, I believe that there is not; but a patient who is suffering from functional diseases or disturbances might give such symptoms.

Q. Would it be possible to diagnose upon such a statement of symptoms?

A. No.

Q. Is a current of the type described to you delivered in the manner described to you of any value in the diagnosis, treatment, cure, prevention or mitigation of the condition known as Hardening of the Arteries?

A. No.

Q. Why not?

A. Hardening of the Arteries is caused by a deposit of calcium, chalk, and a fatty degeneration in the wall of the blood vessel and such changes are irreversible.

Q. You mean once having taken place they cannot be brought back to their original condition?

A. Yes.

Q. Is there only one type of heart disease or more than one type?

A. More than one type.

Q. Are they all dealt with in the same way, or are different treatments used?

A. They are dealt with in different ways and different treatments.

Q. What are some of the general conditions known as heart disease?

A. It results from high blood pressure; it results from hardening of the coronary blood vessels that bring the blood supply to the heart muscle; heart disease due to rheumatic fever, in which there are leading valves; heart disease due to syphilis; heart disease due to congenital abnormality; and heart disease due to vitamin deficiencies.

Q. In your opinion, would a current of the type described to you in the manner described to you have any value in the diagnosis, cure, treatment, mitigation or prevention of any type of heart disease?

A. No. It would not only have no value but it might be dangerous to use in a diseased heart because it might cause a disturbance of rhythm.

Q. Would the current described, delivered in the manner described, have any value in the diagnosis, cure, mitigation, treatment or prevention of the disease known as diabetes mellitus?

A. No.

Q. I ask the same question in regard to tuberculosis, any type?

A. No.

Q. The same question for hay fever?

A. No.

Q. The same question for low blood pressure?

A. It might cause a rise in blood pressure, indirectly, because a patient who receives stimulation may show changes in his blood pressure; but we don't treat blood pressure primarily, we treat the disease which may cause change in blood pressure.

Q. With whatever rise in blood pressure you had would it be of any lasting effect?

A. No.

Q. Would the current of the type described, delivered in the manner described, have any value in the diagnosis, cure, mitigation, prevention or treatment of the disease known as ulcerated colon?

A. No.

Q. What is the treatment?

A. Ulcerated colon is caused by diferent base entities, for instance, little or tiny bacteria known as bacillus, which will produce ulceration of the colon; then there are ulcerations of the colon which will develop and we do not know for sure what the cause is. It is being studied extensively by Dr Bargai at Mayo's and it is associated with the unusual diphtobacillus. There are many different causes of ulceration of the colon and the treatment of each is different.

Q. Would a current of the type described delivered in the manner described have any value in the handling of nerve conditions?

A. Only through its psychological effect.

Q. Explain just briefly how that might occur.

A. We often find a patient who is sick and discouraged and when a doctor shows him attention and becomes interested in his illness and helps him psychologically he may improve a great deal and that would be reflected in his physical condition.

Q. In your opinion, based upon your training and experience, would the current of the type described delivered in the manner described have any mysterious or miraculous results?

A. No.

Q. Has it been your experience that there is any one diagnostic or treating device which is "never failing" and which is infallible for the diagnosis and treatment of all diseases?

A. No, indeed.

Q. Doctor, is hay fever infectious?

A. No, hay fever is not infectious. An infectious disease is caused by bacteria infecting the organisms, and bacteria may infect the body and hay fever result as an allergy to the bacteria itself; that is, it may be an idiosyncrasy on the part of the patient.

Q. Is arthritis fatal?

A. No.

Q. Does insulin neutralize the sugar in the body?

A. It turns the sugar into energy.

Q. If a diabetic patient has a steadily rising blood sugar is it necessary to increase the amount of insulin administered in order to keep the disease under control?

A. Yes.

Q. If the blood sugar of a diabetic is constantly and progressively rising is the amount of insulin which may be given limited?

A. No.

Q. Have you had any tests of the machine known as sinuothermic made under your supervision upon patients?

A. Yes.

Q. Will you tell us how the patients treated with the machine, how their conditions were diagnosed?

A. In order to test these objectively, we tested two patients at the Duval County Hospital in early January of this year; one was a white male, about fifty years of age who had cancer of his leg which had developed some two or three years ago, and he was given the treatment with placing the electrodes on the leg and turning on the current until he felt the tingle and was not uncomfortable, and this treatment was repeated daily for —I have the statistics written down—for about ten days, I believe; and then following that treatment an examination of the patient was made which showed the same diagnosis as was made before the treatment, which was cancer of the skin. The other patient was a negro male who had advanced tuberculosis. He was diagnosed as such in January of 1946, was admitted to the hospital, to the Duval County Hospital in Jacksonville in early January, 1947, the diagnosis having been made by X-ray, physical examination and examination of the sputum.

Q. I hand you X-rays and ask if you can identify those as having come from the patient.

A. Yes. This X-ray (indicating) taken of this patient, whose name is Julius Anthony, was taken on the 30th day of January, 1946 and shows bilateral, that means both sides, advanced tuberculosis of the lungs.

Mr. Goodrich:

I want to have this X-ray identified as No. 5567, Duval County Hospital.

A. This (indicating) is an X-ray of the same patient taken June 4, 1946, which shows slight changes toward improvement, but only slight changes. There is still advanced disease on both sides of the lung.

Mr. Goodrich:

For the purpose of the record, this is X-ray No. 5567 of the Duval County Hospital.

A. This X-ray (indicating) taken in stereoscopic views, which is two plates taken at the same time, and this was taken on January 22, day before yesterday, after treatment with the machine just referred to, and this X-ray shows no appreciable change over the X-ray taken in June, 1946.

Mr. Goodrich:

These X-rays all have the same number, but different dates shown by Dr. Merritt upon the X-ray plates.

Q. Did the current demonstrated by this machine on the tuberculosis patient cause him to cough and expel the sputum from his lungs?

A. No.

Q. In your opinion, based upon the use of the device, did it in any way alter the condition or the course of either of these diseases?

A. No.

Mr. Goodrich:

You may inquire.

Cross Examination.

By Mr. Pemberton:

Q. Doctor, the two cases that you have just referred to constitute your total experience with the sinuothermic devices?

A. Yes.

Q. Did you ever have any instruction in any form from anyone familiar with the machine as to the use of it, or just assume—?

A. We read the directions that came with it and we also read the papers and the technique as described by the defendant.

Q. What papers were those?

A. Papers that were issued in Tampa and that I have read.

Q. You mean for sinuothermic?

A. Yes.

Q. Other than that, that literature, you have received no instruction as a doctor with respect to the study of it, as you would for instance if you were going to go off and take up the study of Roentgenology, or any other field that required an experiment?

A. No. That is a part of the instruction in medical science. It is not believed that that is an adjunct toward treatment of disease.

Q. What is not an adjunct?

A. That machine.

Q. You have neither from Dr. Urbuteit nor anyone else received instructions; you otherwise guessed as to how to use it and did the best you could?

A. I would not say "guessed". I would say we used it acording to the desired technique.

Q. Is that circular entitled, "The Road to Health"?

A. Yes.

Mr. Pemberton:

That is all.

GEORGE R. FOWLER was caller as a witness on behalf of the United States, and, being first duly sworn, testified as follows:

128 Direct Examination.

By Mr. Goodrich:

Q. State your name and address.

A. George R. Fowler; Jacksonville, Florida.

Q. By whom are you employed?

A. By the United States Food and Drug Administration.

Q. In what position?

A. As a food and drug inspector.

Q. Did you on January 22, 1947 have occasion to go to the Duval County Hospital and take a photograph of any kind?

A. Yes.

Q. Will you tell what you photographed at that time?

A. A person's leg.

Q. What was the person's name?

A. James Love.

Q. I hand you four photographs and ask if you can identify those as the ones you took.

A. Yes, these are the photographs that I took.

Q. Do these photographs truly portray the conditions which they purport to represent?

A. They do.

Q. While you were present at the Duval County Hospital did you learn the name of this patient whose picture of whose leg you took?

A. Yes.

Q. And did you learn that he was the patient who was treated with this sinuothermic machine by Dr. Merritt?

A. Yes.

Mr. Goodrich:

We offer in evidence the photographs identified by the witness as U. S. Exhibit No. 19; we also offer the X-rays identified by Dr. Merritt, which will be U. S. Exhibit No. 18. We would like to offer in evidence also, for the purpose of the record, the two sinuothermic machines about which the witnesses have testified. They are present in Court and they are numbered "X-8" on the small machine, and "T-20" on the larger machine.

Mr. Pemberton:

No questions.

(Thereupon, the witness was excused.)

Mr. Goodrich:

The Government Rests.

JAMES C. PEARSON was called as a witness on behalf of the defendant, and, being first duly sworn, testified as follows:

129 Direct Examination.

By Mr. Pemberton:

Q. State your name and official position, please.

A. My name is James C. Pearson. I am Chief Inspector of the Atlanta Station of the Food and Drug Administration.

Q. What territory does that station cover, Mr. Pearson?

A. Roughly, the states of North Carolina, South Carolina and Georgia, and Florida.

Q. Do the inspectors out of your station work under your direction and make reports to you?

A. Well, they work under direction of the station and make reports to the station, as a rule. The direction may be from me or someone else and the reports may be received by me or someone else.

Q. Are you in position, by virtue of your knowledge and position, to state how many formal patients of Dr. Fred Urbuteit who have been treated with the sinuothermic device have been interviewed by you or any of your inspectors since this suit began?

Mr. Goodrich:

We object on the ground of immateriality.

The Court:

Objection sustained.

Q. Mr. Pearson, do you recall in the month of December, of 1945, when a hearing was held in your office in Atlanta under the statutory provision of the Pure Food & Drug Act, at which time I, on behalf, as counsel of Dr. Urbuteit, made an explanatory statement in the record and he was questioned and examined, and at that time an offer to your Department, the Pure Food & Drug Administration, to enter into any form of test or furnish any information was made, and that we would be open and available at all times and hoped you would avail yourselves of it?

A. I remember the hearing.

Q. Do you remember that such a statement and offer was made?

Mr. Goodrich:

We hesitate to object, but believe the statements made by counsel are self-serving and have no purpose in the record.

The Court:
Objection sustained.

Mr. Pemberton:
No further questions.

(Thereupon, the witness was excused.)

DR. FRED URBUTEIT, defendant, was produced as a witness on his own behalf and testified as follows:

131 Direct Examination.

By Mr. Pemberton:

Q. Dr. Urbuteit, state your name and address.

A. Dr. Fred Urbuteit; 307 W. Euclid Avenue, Tampa, Florida.

Q. Are you a practicing Naturopathic physician?

A. I am.

Q. I wish you would, without the necessity of repeated questioning to bring it out, narrate to the Court the training, both in school and under instruction of medical teachers, the training that you have had that leads to the practice of your profession.

A. In the beginning, having been born deficient, my whole life has had to lead toward doctoring to keep me living. At the age of nine I was taken to a specialist who had no hopes at all for my future. He told my parents in front of me that by the time I would be sixteen—

Mr. Knight:
Object to the witness stating hearsay evidence.

A. This is not hearsay. At that time, this specialist took me under his tutorship—

Mr. Knight:

Object. His personal history has nothing to do with his training.

The Court:

I don't know whether he started his medical training at the age of nine or not. Objection overruled.

A. (Continuing.) I began under his tutorship with the idea of learning enough to keep myself from the eventuality or the inevitability, as he put it, of becoming deaf, dumb and blind and not reaching the age of maturity. From his tutorship I became the interpreter of a German professor of surgery. Several years of his tutorship gave me the insight of bodies who had died of various diseases. After that, I had completed a course in Naturopathy, which teaches nature and the way to keep the tissues normal. That was in the American School of Naturopathy. I later took up an advanced course of Naturopathy in the Southern College of Naturopathy. Then I'd taken up the study of medicine, direct, in a school which was duly chartered but not recognized by the medical fraternity, known as the Northern University. Then I'd taken up a correspondence course in electricity and also in drawing to make me capable of drawing the pictures of the various organs for the purpose of text books. Then I had passed the Civil Service examination as a teacher of mechanics. I guess that about covers it.

Q. When did you begin the practice of Naturopathy as a profession?

A. In 1926, in Tampa, Florida. In 1927 a Naturopathic Bill was passed in the State of Florida and I think it was early in 1928 I was physically able to go to Jacksonville to take this examination, and passed with a very high average. Since then I have been practicing Naturopathy in Tampa, Florida.

Q. You were admitted to practice in 1928?

A. Yes; under the new Bill which was passed in 1927.

Q. And you have the whole time since been a licensed practitioner?

A. Yes, right in Tampa.

Q. Dr. Urbute:t, if you will, describe for the Court your experiments leading to the development of the sinuothermic device.

A. While I was intepreter for this German professor of surgery, he could open a body which had expired from tuberculosis—

Mr. Goodrich:

Object to that, unless some basis can be shown that the man had tuberculosis at that time. That would be hearsay.

The Court:

Objection sustained.

A. (Continuing.) At that time I conceived the idea that if a medium could be found which could agitate or amplify function when function slows down and can be brought back to its normal function, if that medium could be found it would be a wonderful thing for humanity-at-large. And I went on to search for it, which made me study all the various things leading to such a device. But the device was not perfect within its present form known as sinuothermic until my body was completely emaciated, which had set in with the advanced stage of arthritis. And when I was in that stage my body being so highly sensitized I could feel the direct waves emitted from a portion of the instrument that was imperceptible to the human feeling, same as an electronic instrument. Knowing it was feeling a bit too course to harmonize with the body I called in an associate of mine who was

versed in this work to make the necessary changes for me until they soothed my body rather than irritated it. Then the next thing was to make an instrument that would pick up these waves, which was afterwards perfected so they could be directed to any portion of the body and by the proper amount of volume it will amplify the function which is placed upon it. That is the present condition of the sinuothermic instrument today. Through its energy it has the phenomenal ability to amplify the function of the organ which it is placed upon, providing it is properly used. A novice to take that, without instruction, could not be expected to use it the same as someone who was familiar with it. The same holds true of anything. A Roentgenologist has to learn his work before he can practice with his X-ray, and the same holds true with sinuothermy. If a person is taught sinuothermy sufficient that they can use sinuothermy upon themselves for any specific disorder they will get results accordingly.

Q. Doctor, the sinuothermic device has been described to consist simply of a transformer, so far as the basic unit of it has been concerned.

Mr. Goodrich:

It has been explained that there are two parts, the potentiometer and the transformer.

Q. One item referred to is the transformer, the thing that changes the current, will you state just what this unit consists of?

A. The potentiometer that has been mentioned is merely a means of controlling the quantity of the electrical current which enters the sinuothermic unit. Our first machines, before there were potentiometers made, we had a mechanical control which had nothing to do with the potentiometer. The sinuothermic unit, itself, while it is a step-down transformer, but every instrument that has ever been made that reduces the current, which

has a current, is a step-down transformer. And as has heretofore been stated, that there are a number of different kinds of transformers and each one does its own particular kind of work. That holds true also for sinuothermic. Sinuothermic is not just a thing known in the field of electricity as a common step-down transformer. I had a common transformer manufactured by a manufacturer in Tampa; I ordered it over the telephone, to give me the same voltage that we have in sinuothermic. He did that. I used that transformer on myself. I put it in the cabinet and used it exactly as I would sinuothermic. I have the misfortune of having one kidney that needs attention all the time. Periodically it gives me a lot of trouble. I tried this transformer, which was a common transformer, on my bad kidney and it caused such severe pain that I had a hot water bottle on it all night and could not stop the pain and the next morning I put sinuothermic on it and in less than thirty minutes I had relief. That shows there is a physiological difference between a common transformer and the sinuothermic transformer.

Q. Is the transformer in this cabinet (indicating) the one you just referred to as having used?

A. Yes.

Q. It is the regular commercial type of transformer?

A. The regular commercial transformer; rigged up exactly as sinuothermic; the only difference is in the unit itself.

Q. When did you have this made?

A. I don't remember exactly the time; it seems along in December, 1946.

Q. While this case was pending?

A. Oh, yes, just recently.

Q. And when was it that you used it on this test that you referred to on yourself?

A. Shortly after I received it; it was in December some time.

Mr. Pemberton:
The defendant offers this for inspection or evidence, whichever it can be used.

Mr. Knight:
This is not the same machine as this small one (indicating).

Mr. Pemberton:
No, an entirely different machine.

Mr. Knight:
Identify it by number, so there will be no confusion in the record.

Mr. Pemberton:
This is No. T-5, it is stamped on the cabinet.

Q. Prior to the development of the sinuothermic device which you found to be effective, did you make numerous experiments in the winding of different kinds of coils or transformers and experimenting with them?

A. Yes. For a number of years I have wound up all kind of instruments, seeking that which I was after, to amplify function, until I finally got the winding that I have in the sinuothermic instrument, which I dare say is different from anything that I have ever heard of or seen in the field of electricity.

Q. Did you ever find that any of these other instruments or transformers or coils that you made were effective for the use of the body?

A. None, whatever.

Q. Have you experimented in different ways in making the device that you now have, or to make modifications in its winding, core, and so forth, and trying to improve it, and find anything from that?

A. Yes. By using a different kind of a core gives me a different physiological effect upon the body. You can make a core out of most any kind of an iron, but each one has its own peculiar kind of effect.

Q. Has the sinuothermic device been accurately described by any of the witnesses put on by the Government?

A. No.

Q. They have not described its exact construction?

A. They have not.

Q. Now, I believe you stated you began the use of this machine on other people—was it 1927?

A. In 1927 I began practicing—or 1926. I had given a series of tests to other folks who volunteered and in each one of those they gave me a wonderful report as to their improvement. For several years I thought that the people were only psychologically being treated, but a constant repetition of this from thousands of people was enough to make the worst skeptic in the world realize that there was something being done constructively.

Q. Have you kept a record of the patients that you have treated by this sinuothermic machine?

A. Yes, I have. I have the records, their diagnosis and their previous statements, as well as what we have done for them.

Q. Approximately how many patients would you estimate you have treated with the sinuothermic machine?

A. That would be hard to estimate, but in round figures I would say perhaps ten thousand.

Q. Does this trunk over here contain the card indexes of diagnosis and treatment card for each patient?

A. Yes. There is a card in there for a good number of the patients that I have treated, with their diagnosis.

Q. In your experience in treating people with the sinuothermic device have you ever found any patient who was adversely affected by the machine?

A. No, I haven't found anyone adversely affected, although there was a number of nervous conditions that have come to me—oh, they were either frightened, or they had a mental allergy towards electricity, but after a treatment or two their nerves calmed down. Whether it was the effect of the machine, or psychological, would be hard to determine, but the physical disorders that had been found originally did disappear.

Q. No one has ever suffered any, shall we term it any "accident", anything whereby they were damaged in any way by the machine?

A. Absolutely not.

Q. Has anyone ever complained of discomfort or been affected in any sense in the treatmen?

A. Oh, yes. I have one patient in particular. He had a stone in his kidney and in dropping that stone down he had excruciating pain until it dropped into the bladder.

Q. But normally, from the mere application of the pads on the machine and the energy transferred there is no pain or shock?

A. No. It has a tendency to allay pain; serves as a sort of anesthesia on painful organs.

Q. Doctor, I wish you would describe to the Court your method of diagnosis of any person and in which manner you use the sinuothermic machine in diagnosis.

A. I use all of the accepted ways in diagnosing; but, as a concrete example, in 1934 I went to New York to put on a demonstration there at the College Hospital, the National College Hospital. There were a number of doctors there taking post-graduate work at the time and they brought to me one little patient. I examined her with the stethoscope and her heart was so rapid it sounded like it was trying to pump out through her body. I examined her in the usual way and then demonstrated to these doctors how I would examine and locate the

actual cause of this heart condition, by applying sinuothermic. I picked one contact as far removed from the condition as I thought would be practicable, and I used the other one then to explore with. In the exact spot where the lesion was, which was evidently causing her trouble, there was a reaction, a physical reaction noticeable in the patient, that is, by their actual muscular contraction, and it also registered on the meters. The professor, himself, was amazed at finding this particular spot. I put the treatment on that spot. The professor was on one side of the cot and I on the other, each of us with a stethoscope on that woman's heart. In twenty minutes he reached over and tapped me on the back of the hand to let me know he recognized the change in her heart action.

Mr. Goodrich:

We object to this, it is hearsay.

The Court:

The objection as to what the doctor told him when he reached over and tapped his hand is sustained; but what the witness, himself, says is admissible.

A. (Continuing.) The patient, after forty-five minutes of treatment, got up from that cot and walked out by herself. They carried her in. It was afterwards learned she had been in the College Hospital for nine months under various treatments and examined by all kinds of doctors, with no avail. Now the condition that caused that heart to go out of line, just above the gall bladder, under the ribs, on the right side of the body, there was a congestion there. By opening that congestion through amplification by sinuothermy the strain was relieved from the heart that was causing the heart to exhilarate itself and the heart action came down to normal. That

was in September of 1934. And in the Spring following I had a letter from that patient stating that—

Mr. Goodrich:
Object to that, it is hearsay.

The Court:
Objection sustained.

A. (Continuing.) That is all on that.

Q. Go a little further and describe the use of this sinuothermic machine in diagnosis, the method you use, the things that have been referred to here as meters in arriving at the conclusion of your diagnosis of the human body.

A. The human body varies in construction and function. By placing one electrode in a remote part of the body while examining some other portion of the body with the other, when the energy is turned into the patient wherever there is an abnormality that patient responds a characteristic pain of that particular ailment, even though the ailment itself is painless within itself; but when the energy is turned on, which amplifies its function, the amplification of that function not only registers on the meter to the extent of the lesion, but it also is dominantly felt by the patient himself. The patient can then direct the doctor as to how deep it is, although the doctor, himself, knowing anatomy, will know it; but the patient, not knowing anything about anatomy also knows it, so it really is an educational as well as an effective diagnosis for the patient. Now, where there is normalcy in functioning, it merely, according to the amplifaction, I mean the amount of volume, according to the amount of volume placed upon the patient, you can amplify its function up to any degree of tolerance to the patient; but where there is an abnormality, such as inflammation,

the energy can't get through that particular portion, like hitting up against a block, while its normal energy flows right along; but when it strikes an obstruction it stops there and give the patient a feeling of the characteristic pain of the particular ailment itself, and that also registers on the meters the amount of intensity or resistance there is in that particular area.

Q. Have you learned by any experiments in the use of the sinuothermic machine to judge by the indication on the meters the condition which is existent in the patient to whom sinuothermic is applied?

A. I don't believe I understood that question correctly.

(Question is read to the witness by reporter.)

A. The meters do not tell me what the aliment is, it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of obstruction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is. One party called up and wanted to know if the machine would talk. I said, "No, it is not a talking machine, it merely registers the cause, shows you where the cause is, and then by amplifying that particular area you do overcome that cause and then the condition is normal."

Q. By diagnosis, you don't mean that has a dial with letters on the face and the needle points to it, or some such thing as that; but simply an electrical indication by which the person familiar with the instrument and its use can judge the condition of the patient.

A. That is correct. There is no way of registering the kind of an ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever

that something is wrong it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. But I find in all my experience it is not necessary to go to all that trouble to take those tests. As long as the patient gets well, that seems to be the first requisite.

Q. Dr. Urbutéit, the circular entitled, "The Road to Health" introduced in evidence conveys, I will call them "case histories" or statements about individual cases. Do you have the same printed copy as that?

A. Yes.

Q. Willl you take those various histories, beginning with the first one, and briefly, without stating what the people told you, but simply actually what you found to be the trouble and what you did and what the results obtained were, and name the individuals if they are not already named in the circular.

A. I have heard the witnesses down here and it was referred to as something magical. Here's an article in the second column, headed, "What is Incurable." (Reads.) "But because Sinuothermic has the ability to amplify function and thereby locate and remove the cause it makes one wonder just what is incurable. Sinuothermic locates the cause; in cases of complication of disorders there are more than one general cause, but no matter how many causes there are, Sinuothermic will locate one after the other until the whole combination is under control. No matter what you do or take for your ailment, unless it helps nature you will not get well. Sinuothermic helps nature by amplifying natural function. It is all very simple. If your muscles are underdeveloped, exercise will in all probability develop such muscles; if an organ does not function it begins to atrophy because of its inactivity but Sinuothermic restores this activity just as exercise builds up muscles, that is helping nature. It is a great puzzle to the average person how

Sinuothermic can do such wonders, but when you stop to think, nature takes a new born baby and makes it grow into a man or a woman—"

Mr. Knight:

We object to the witness continuing to read from that general paper. It is not responsive to the question.

The Court:

I think the Docor in his testimony has stated in substance what he is now reading.

Mr. Pemberton:

The question was to take up specific individual cases and to deal with them.

A. The first column here, "Painful Breathing". This woman came to me like it is stated up above in the article, and had been diagnosed as an abscess in the liver—

Mr. Goodrich:

Object to what any other person had diagnosed the disease as.

The Court:

Objection sustained.

A. This patient was found to be suffering from merely a cramp of the muscle which was causing the stabbing pain in her chest. just like you would have a cramp in the calf of your leg. it can be awfully uncomfortable if you could not straighten the cramp, and in less than ten minutes that cramp was broken. There was nothing organically wrong with her. She merely had that cramp. It could have been caused by one or a lot of things. That is enough on that.

Mr. Goodrich:

I don't believe the witness stated the name of the patient.

A. Her name is "Trowell". Now in this fourth column this "Mysterious Ailment". This man was brought to me, the article explains the whole thing, it won't be necessary to go through that, but this man was brought to me in a very bad condition, suffering with abdominal pains. The examination revealed that he had a small rupture just about the gall bladder which oozed the bile between the tissue and emptied over into the stomach, and this bile mixing into the stomach fluids after it got down to the lower intestine caused excruciating pains like indigestion, although during these spells he would refrain from eating and drank as little as possible. According to his history he had been having those pains for twenty-five years, off and on. By locating this particular spot with sinuothermic, it could not be located with the fingers, I examined him in every way, shape and form before applying the machine, but the machine showed the reaction and by one treatment on that spot stopped his pains. He came in the next morning on his own power and completely relieved of his pain. Since that trickle was stopped into his stomach and went down through the gall duct where it belonged his pains immediately ceased. I treated him approximately three weeks and I have seen him time and time again since then and he has never had a return of that trouble.

Mr. Goodrich:

We object to the witness outlining pain that some other patient might have had. He has no means of knowledge on that subject.

The Court:

That is part of the history of diagnosis, what the patient told him. Objection overruled.

A. His name is Tom Richardson. Now, in column seven in this same paper this woman came to me for diagnosis and I diagnosed her case as completely covered, the whole abdomen practically completely covered with cancer. She had a rigidity from the pelvic to the ribs; there might have been one or two little spots that had a little softness in there, but the rest of it was built up with a cancerous tumorous formation. That woman was active, working, never knew that she had an ailment, but several years later when this ailment began to bother her she had undergone two major operations. They found her to be exactly like I had described her.

Mr. Goodrich:

Object to that as hearsay, what they found her to be.

The Court:

Don't inject anything that anybody told you.

A. That is the history that is related here in the paper, so I thought it permissable because they have taken the paper as an exhibit.

Mr. Goodrich:

I don't believe he has the right to prove that by hearsay declarations.

The Court:

He is not doing that. He is talking about its being exactly the same as his diagnosis. The objection is sustained so far as what anybody told him. This is a case being tried by the Court and naturally I presume I have sense enough to eliminate what is not admissible.

Mr. Pemberton:

I have refrained from objecting because of that very fact to the very broad testimony that has been brought out by the specialists. I might as well explain now that I have not gone over what any witness would have to say and rehearsed with them what they are going to say.

A. This woman, after having had two major operations and various X-ray treatments, her pains became unbearable, then she came back to me and asked me to save her life. She said that she could not possibly—.

Q. Don't tell what she said.

A. It is here in the article. When she returned there was no possible hope for her. We could relieve her pains considerably, but not for long at a time. I think I treated her about two weeks and kept her reasonably comfortable,, but she took narcotics continuously; but the treatment did have a palliative effect upon the pains temporarily, and like I knew she would she died shortly afterwards.

Q. What is the name of that patient, Doctor?

A. I will have to look at the records to get her name. She has a peculiar name.

Q. Take up the next case and describe it.

A. Now, in the last column of this page we have a case of Diabetes. This girl, only sixteen years old, came to me with a case of Diabetes. Her father came and made the arrangements for her treatments. She was taking then considerable insulin each day and her menstruation had ceased for nine months or more before she came to me. Diabetes can be caused by more than just one disorder, but the real disorder is in the pancreas. The pancreas supplies the natural insulin, burns up the sugar in the body, and when it ceases to function for any one reason then you have Diabetes. But assuming that the pancreas was functioning properly and you have some other dis-

turbance, for instance in the liver, you also can have a form of diabetes. This girl, after several treatments, could leave off half of her insulin; I think the first week she left off half, because the full amount created a certain amount of shock so she cut down according to the shock that the insulin was causing. And then her menstruation after several months began again. Why it began, I don't know, but she did go to work and she worked after she was through school and worked for several years until she got married. That girl's name is "Hart". Here's one here with a picture of a woman who had cancer behind one of her ears up on her head. That cancer had eaten down the side of the neck and up under the one eye. By treating with sinuothermic, I treated her constantly, all day long, just knocked her off long enough for lunch and then back again, all day long for seven weeks; but in that time the indication of discomfort down in her neck and in her eye had disappeared and it was localized then back of the ear on the skull, itself. I treated not directly on the sore, but as close to it according to where the discomfort was and I could get any reaction. The energy from the treatment would enter up into where the ailment was, where it was centered. The expulsion of that cancer was gradual. It came on up and up and up. There was a piece of the skull was loosened all around, quite a good sized piece. By raising the edge of that you could see the pulsation underneath and gradually new bone grew under that piece before it was removed entirely. I took great care so that nothing could enter into that cavity and after the bone was grown across there was only one little piece that was adhering and for a time I thought I might have to help it out with an instrument, but it finally, as the tissue grew underneath it, it released that corn and it came out of its own accord. That woman is still living, Mrs. W. J. Porter, and her whole testimony is there and she still is in good phy-

sical condition. Now, on the other side of the paper we have another peculiar case. Her picture is also here, with her full name, Mrs. J. A. Lipsey. Her daughters brought her to me. Her eye was protruding and the poor soul was suffering so terribly with that eye being pushed out by a growth back of the eye. The diagnosis of other doctors, as she has told here, didn't give her a chance.

The Court:

Don't tell what the other doctors said.

A. (Continuing.) Anyway, the first treatment allayed the pains. I don't remember the length of time she came for treatment, but I would say several months. I have the records there. In three or four weeks, whatever it was, maybe on two weeks, her eye had receded. That showed that the tumor had also disappeared. What caused that tumor, nobody could foresee and nobody could tell, at least I could not, but it was there, and as it receded the eye receded back into its socket and her picture is there and it tells you here whether it was one or two weeks, whatever it was. And until today she is a well woman and has never had a return of that trouble. Now, here's another testimonial from Mrs. J. F. Sumner. That is the last one on this side of the sheet. This woman came to me looking for a position as social secretary that I had advertised for, and when I looked at her I see the woman is in a critical physical condition. I asked her for the privilege of examining her heart. Her heart was so bad I thought she would die before getting home. I told her she should be in bed. She told me she had been in the hospital off and on for several years and I told her I thought I could probably help her with Sinuothermic. I told her if she would come back by two o'clock, that was along ten in the morning, if she would be back by two o'clock in the afternoon I would take her as a patient.

She had already let me know she could not pay for it, I said, "That does not matter". She came back before two. I didn't think she could live much longer than that. I started to treat her. I think I treated her several years all together. The specimens which she passed was almost as much as a newborn baby, vaginally; and the condition of the intestine and colon, the cancerous condition began to drain down into pus. She passed quantities of pus; she estimated a quart a day. She passed that pus in various amounts for perhaps nine months, before it began not to come every day, probably several days it would miss and a little bit would come. So. I dismissed her after there had been no sign of pus for six weeks. That woman is still living and still doing nicely. I don't mean that she has a big, robust body, but she is living. Now, here's a case of asthma. That is in the sixth column of the back page. This woman came to me with one of the worst cases of asthma that I have ever encountered. Both of her lungs were filled with mucuous, all of the little bronchials were stopped up, and with the same energy applied in the proper place to convulse muscular action she was able to cough up as much as could be gotten out of each treatment. I treated her for about a year. That was in 1927, and she has to this day never had a return of her asthma. Her name is "McClellan". In the previous testimony this article here in column five had been written into the records. I was over in the West Indies at that time and it was in 1922, 1923, the winter of 1922, 1923, and the Captain of Ports, when he learned that I was a doctor, he asked me if something could be done for his son. He had fallen out of the kitchen door at the age of approximately three and one side of his body greatly paralyzed and didn't grow in comparison with the other. His little arm would swing back and forth like a little rubber hose attached to his shoulder. He walked, himself, on his ankle, rather than on the sole of his foot, be-

cause it was twisted so completely out of shape. The father wanted me to make arrangements somewhere in the United States to have the boy treated, but I asked him to bring the boy in and let me examine him. The doctors there insisted upon an operation on the brain. The father would not submit to it because they had no adequate facilities for that kind of an operation anyway. So upon the examination of this boy I located up on the tip of the axis on the atlas itself there had been a jolt there that held that in a slight dislocation, which pinched the nerves which control that side of the body.

Mr. Goodrich:

Where was that lesion?

A. Up on the atlas. I spent the whole afternoon there teaching the father when that was back in place and when it was out. He became quite interested in replacing that when it would get out of place. I taught him how to manipulate that side so as to help in restoring it to normalcy. I left there the next morning and heard no more of the case for eight or nine years, when another one of his sons came there and I asked him how the boy is. He said, "He is taller than I am, and I am six feet, and he is a perfect specimen of manhood". I afterwards learned that he had taken up the ministry and is practicing ministry in Jamaica. His name is "Panton".

The Court:

You didn't treat him?

A. Not with the machine. I merely taught the father how to do that with his fingers and the manipulation on the crippled side. The reason I mentioned that is because it is written in the record. In column one on the back of this paper relates a case on tuberculosis. This man had

had tuberculosis for a good many years. He had been in the sanitarium and they supposedly had arrested the case. That was back in 1904, I believe it was. I have the records there. But in 1929, through his stepmother, he came to me after he had been doomed. The doctors in attendance had given him but three months to live.

Mr. Goodrich:
Object to what the doctors said.

The Court:
Objection sustained.

A. (Continuing.) I treated him. The first treatment expelled quite a quantity of pus formation from the lungs. After he had gotten a deep breath again he asked for the privilege of more treatments, which I had given. When his folks were ready to go back North he asked then for the privilege of taking the instrument along with him to continue his treatments and I granted him that. Today, he is a fine, healthy specimen, recently married, and no further trouble from his tuberculosis condition; while he has some mucuous, but the mucuous is neutral. We had taken several specimens in 1935 after using the instrument for approximately five years and the analysis was negative. So much for that. His name is Delmar Johnson. Now, here is a case of Infantile Paralysis in column three on the back page, the article near the bottom. This fourteen-year-old boy who was totally helpless from his shoulders on down. He could not sit up. His spine would collapse like a string. His head rested upon his shoulders with no visible neck. The grandmother, who had taken care of this boy from childhood on up related that he was stricken at the age of six. When he came to me and I examined him and began working upon him after the tenth day they reported that

he was pushing his little wagon around. Of course, he was not able to walk, he was up on his knees. His spine was rigid enough to hold him up and his neck had come out of his chest and he had a reasonably nice form and he gradually got so he could get up on crutches. I don't remember how many years I treated him; but I have the records there. He went everywhere by himself after he had gotten up on crutches. Before that his grandfather would carry him over his shoulder like a sack of salt, and he had to either lay him down or hold him because his spine would collapse. After he graduated from the Tampa Parochial University he came here to Gainesville to the State University by himself, unattended, studied to be a Certified Public Accountant. His records will be here to show that that is true. The grandmother, who would gladly come here and testify to the authenticity of this has misfortunately died this New Years Day. I talked to her just before Christmas and she related the whole story to me again and stated that the Priest of the school would be glad to testify to its authenticity. That boy came home on the Christmas vacation and had an accident in Tampa on the Bayshore Boulevard and was burned alive on the back seat of the automobile. I don't remember what year that was—seven years ago. His name was Jack Shea. Now, here is a case in the fourth column, on the top, a case of arthritis. This man was in his seventy's, or thereabouts, and had been seeking relief from his arthritis to no avail. He came to me through the recommendation of a woman where he was rooming, and the article explains how it all came about. I was reading the wrong one. However. I don't think it was over two weeks of treatment when he was able to walk by himself without crutches. This man to today has never had a return of his arthritic condition and he is in better health than he said he had been in a good many years. That is enough

on that. His name is "Hutchinson"; I don't remember his first name; "C. L.", I think his initials are. Here is one on prostate trouble. The first column, near the bottom. This man had had a complete stoppage of the urinary canal. His bladder was so full and the urethra was so tightly closed that a catheter could not be inserted. I treated him with Sinuothermic until some of the swelling had receded sufficient to put a soft rubber catheter in to draw off the water; and after the bladder had been emptied we finished the treatment. When he came in the next morning he was able to void normally. I treated him then until his prostate was completely well and he has had no further trouble until today. His name is "Lindall". Here is a man who came to me with supposedly prostate trouble. He had been suffering for years and toward the last he strained so hard to urinate that it would move his bowels. He was from Detroit. I can't recall his name, but it is on the records. When I examined him with Sinuothermi I determined that he did not have prostate trouble at all, but had a small tumorous formation right at the exit of the bladder. My advice was that he should have it removed surgically, which he did, and in a few days he was well enough to travel back home all well. He asked me if I could remove that with Sinuothermic. I told him that perhaps I could, but it would not be practicable, it would probably take weeks and weeks to remove that little thing because it was so difficult to get at direct, while with a little surgical operation he would be rendered well within a week, which he was. Here is a man here in the second column near the bottom. This man had various cancers on his leg similar to those on that photograph that had been offered in evidence. He had been given up as hopeless like cases like that usually are, but when I examined him I found it was not the leg itself that was at fault. His fault was up in the abdomen and by the proper Sinuothermic treat-

ment upon the abdomen we had gotten the pus running out through the colon; and being excreted in the natural way, without touching his legs at all, his legs got well. It has always been my assumption that everything has a cause; that if that cause can be properly located and remedied Nature will take care of the rest. That is enough on that. I will have to look his name up. I would like to say a little more on Mrs. Sumner's case in regard to appendicitis. During the years that she was being treated off and on she had developed a case of appendicitis. They called in their usual physicians, but her heart was so bad an operation would be impractical and perhaps fatal. They brought her to me and with one Sinuothermic treatment the appendix was opened. I treated her several hours, probably four or five. She went on home and before morning passed the pus had been excreted in the appendix. This woman at another time during those years had had a paralytic stroke. They brought her out to me in an ambulance. She was badly distorted; could not speak her face was distorted, one leg drawn up behind her and an arm drawn up half-way to her neck, and her heart was so bad at that particular moment it looked like she would die before I would do anything constructive. But I hurried and examined her and found the first lesion and put Sinuothermic on her, and examined further and in a short time had several Sinuothermic instruments on her at the same time. Where I found the different lesions I put an instrument on to break up the lesions. In thirty minutes, or so, she became relaxed and in due time she was back to normal and able to speak. She was able to get up off that cot by three o'clock in the morning, or thereabouts. I had begun somewheres around eight or eight-thirty in the evening. I think that is enough on that.

(Thereupon, a recess was had for lunch until two o'clock in the afternoon, at which time the witness was recalled to the witness stand for further direct examination and the following proceedings were had:)

By Mr. Pemberton:

Q. Before the Court recessed you were discussing the individual cases that were mentioned in the circular that was introduced in evidence. Now, I will ask you the general question, are each of the events referred to or related in that circular based upon actual facts, are they true statements?

A. They are. They are, all of them. Here is one that I would like to draw the attention of that had been given as testimony before. "Hay Fever Infection", one that I missed this morning while I was going over these. This woman who is related here in the paper as having had hay fever infection, I wist to make it clear to the Court what I mean by hay fever infection. This woman has had hay fever for forty-eight years, according to her own statement, and at this particular time when she came to me her eyes were so highly inflamed they were just as red as blood itself. The examination revealed that she did have hay fever and this eye infection was caused, as near as could be determined, by the mucuous of the nasal passage being wiped into the eyes with the handkerchief; therefore it caused the infection of both eyes. After several treatments with the Sinuothermic instrument the eyes cleared up and she was cautioned never to use the same handkerchief to wipe the eyes and the nose while the hay fever was active. But to my personal knowledge, in all of the years since then, this woman has never again had an attack of hay fever. That is all on that.

Q. Doctor, will you state to the Court your own epperience, I mean on yourself, in treating yourself with the Sinuothermic machine after you had developed it?

A. At the time that the Sinuothermic machine was finally in its perfected stage I was down myself after having been completely emaciated by universal muscular atrophy following an attack of arthritis deformans; and while in that stage, after I had already testified that I had called in assistance to make the corrections necessary in the energy emitted from the instrument, at that time I had large deposits on either side of my knee joints. Perhaps I used the wrong quotation there. I mean I had so dislocated my knee to where when my thigh was in alignment my feet were approximately twenty-four inches apart. With constant treatment of all my waking hours and a good deal in my sleep I have rebuilt those joints, as you can see I have a fairly good action there (exhibits to Court); outside of the cords being caught underneath, which I haven't been as yet able to loosen up. This arthritis deformans removes bone tissue from one part of the body and deposits it in another part of the body. It eats out the joints. This joint here (exhibits to Court), in my right hand, had been completely gone. You could touch between the bones and touch the skin in between as there was no bone left. The only joints so far that I haven't reconstructed with the use of Sinuothermic are my two thumb joints. This one here (exhibits to Court) is almost built back, but if your Honor will observe this one here is considerably eaten out, as you can see. This one here (indicating) is almost built back to normal. I have the action of the thumb as you can see. This one here, while the muscular action has not been restored in that joint yet, but it is coming. Two years ago that could be bent down at right angles, where you see now it only goes down about 15%. By the constant treatment I have re-established my body. As you can see, I am no longer emaciated. When I was first able to get out of bed and was put on the scale I weighed seventy-eight pounds. When I first began to lose my assimilation and the last

time I was able to get on the scale before going to bed I weighed eighty-six pounds. But gradually I have built myself back to my normal size.

Q. Doctor, will you relate the number of cases—.

Mr. Pemberton:

Your Honor, we have a number of witnesses that can be available to affirm Dr. Urbuteit's testimony as to their particular case and I don't want to burden the Court beyond what you care to hear; but I prefer that any time you feel we have gone as far as you care to go on that line of testimony just say so. So for that reason I will ask Dr. Urbuteit to briefly outline a number of these cases and then bring in these witnesses to confirm the testimony.

Q. Doctor, will you take up several cases of the people here?

A. I have already taken up several of the cases.

Mr. Knight:

I think at this point the Government will possibly save some time. In order for Dr. Urbuteit to diagnose and lay the basis for this testimony it is necessary that he be thoroughly qualified, and if we may examine him along the lines of his qualifications and his history at this time I think it will save the Court some time.

The Court:

I didn't understand that he was going into a diagnosis.

Witness:

They had given the testimony prior to my coming on the stand that this paper is a falsehood and I have given you a resume of what had transpired on each of these

cases, and we have these people here now that you may see them and have them interviewed as you see fit.

The Court:

When you put the witnesses on the stand then will be time for an objection and if you wish to argue the objection at that time. If you do it now it is a little out of place.

Mr. Knight:

I understand that this witness is now going to testify as to a number of these cases that he has there; that would involve a diagnosis and his professional capacity to make that diagnosis.

The Court:

If that is what he is going to do, then I will hear you.

Witness:

As I understand this whole case it is a condemnation of the articles in this paper and I am going to try to show the Court that everything in the paper is all true, and I have the people here that you may see them, who are represented in this paper.

The Court:

That is true, but there are certain rules of procedure you must follow. If it is a question of diagnosis I think you have the right to interrogate the witness to see if he is able to diagnose the cases.

Cross Examination.

By Mr. Goodrich:

Q. Will you state the date of your birth, please?

A. July 26, 1886.

Q. State the name and address of the specialist under whom you studied at the age of nine years.

A. Dr. Dean.

Q. How long were you under his tutorship?

A. As near as I can remember, off and on perhaps eight years or so.

Q. Will you give me the full name and address of Dr. Dean?

A. As near at I can remember, I don't remember his initials, but he was on Spruce Street, I don't remember the number, in Scranton, Pa.

Q. You don't remember his name or initials?

A. Seems like it was J. A., or J. H., I am not sure.

Q. Were you under his tutorship on a part time or a full time basis?

A. I went to school and I was with him after school and during vacation time.

Q. Just exactly how long now?

A. Over a period of perhaps eight years.

Q. And how long per day, or week?

A. During vacation I would say about ten hours a day for six days a week, and after school four a day and Saturdays about ten hours.

Q. Over how long a period?

A. Well during the eight years.

Q. Which would make you seventeen years old when you completed this tutorship?

A. Thereabouts.

Q. Is it "Dr." Dean, or "Mr." Dean?

A. Dr. Dean.

Q. What sort of a doctor was he?

A. Medical doctor, and specialized in eye, ear, nose and throat work.

Q. Was he licensed to practice medicine?

A. Absolutely.

Q. Was all the time spent at his address on Spruce Street?

A. That is correct.

Q. State the name and address of the German professor for whom you were an interpreter?

A. His name, as near as I can remember the pronounciation, is "Butzitser".

Q. How long did you remain under his instructorship?

A. Three years.

Q. What years were those?

A. Well, I was approximately seventeen, you can figure up the years.

Q. That would take you from seventeen through what?

A. Twenty-one.

Q. And were you engaged full time there?

A. Oh, yes, I was engaged full time, and he tutored me through high school at the same time.

Q. Where was he located?

A. He was also located in Scranton, Pa, and his school was in conjunction with an embalming school that was owned and operated by an embalmer named "Kuzik".

Q. He was an embalmer, was he?

A. He was the first embalmer in that part of the country to open a school of embalming.

Q. He was not a licensed physician or surgeon?

A. He was an embalmer.

The Court:

Whom are you talking about now?

A. Kuzik.

Q. Who was Butzitser then?

A. He was the professor of surgery.

Q. At whose school?

A. At his own school, in conjunction with the embalming school.

Q. He ran a college?

A. He had the privilege of the embalming school to do his teaching.

Q. Did he have a course of instruction, or was all the work just observation?

A. He had a course of instruction in animal surgery and osteopathy. He had a special course that he taught in the manipulation of the body by the hand.

Q. And is that what you studied under him?

A. Correct.

Q. For three years?

A. Yes.

Q. What were the dates and period of your attendance at the American School of Naturopathy?

A. I went there, as well as I can remember, I graduated in 1921. I put in three years there.

Q. Where was that school located?

A. In New York City.

Q. What address?

A. The main office is 343 Lexington Avenue.

Q. Did the school move at any time during the period of your attendance?

A. No.

Q. What is the name of the Dean of the school?

A. One Dean is Dr. Paul E. Coles, and another one named—I don't recall.

Q. How long was Dr. Paul E. Coles dean of that school?

A. About a year.

Q. What year?

A. I don't remember.

Q. Was it the year you graduated, or prior?

A. He was there when I graduated.

Q. He was the Dean in 1921?

A. Yes.

Q. Did he sign your diploma as Dean?

A. Yes.

Q. Do you have that diploma available at this time?

A. It is in my office.

Q. Can you name anyone else who signed the diploma?

A. Yes. Dr. Benedict Lust, who was the president of the college, and Louise Lust, who was secretary and treasurer, I believe, something like that.

Q. Did you ever hear of Dr. Antoine Dyninger?

A. Yes, I have heard of him.

Q. Was he teaching at that school at that time?

A. That I could not say, definitely.

Q. Can you name anyone else, outside of Dr. Cole and Dr. Lust, who taught you?

A. Well, it would be easy to look that up.

Q. You don't have that information at this time?

A. Not here with me, no.

Q. What degree were you awarded at that school?

A. Doctor of Naturopathy.

Q. And the date of that degree, exactly, I don't mean the year, I would like to know exactly, if you do know it.

A. No; but it is on my diploma.

Q. When did you finish that school; do you remember that?

A. Now that is all registered on the diploma.

Q. State the dates of your attendance at the Southern School of Naturopathy.

A. Well, that was from 1922 to 1924.

Q. Do you have any more specific dates than that?

A. I started in the beginning of the session of 1922 and graduated in the Spring of 1924, I believe.

Q. Did you graduate April 15, 1924?

A. I imagine that would be the date.

Q. Where was the Southern School of Naturopathy located?

A. In Tampa.

Q. At what address?

A. I don't remember the number, but it is on Highland Avenue.

Q. Would 2410 refresh your recollection?

A. I imagine that would be it.

Q. Do you know as a matter of fact that was Dr. Paul E. Cole's residence and no school was conducted at that place?

A. I think you are a little bit wrong on that.

Q. Was the school a day school or a night school?

A. He had both.

Q. Which did you attend?

A. Both.

Q. For how long a period?

A. Something over two years.

Q. Did you teach at that school?

A. I did.

Q. What did you teach?

A. Anatomy and Physiology.

Q. Can you name any of the others on that staff?

A. Yes. There was a Dr. Gildrich. I don't remember the names of them; no.

Q. How long did you teach at that school?

A. Practically all the time I was there.

Q. That would mean you were teaching there in 1922?

A. I was teaching and taking training simultaneously at different hours.

Q. I show you the 26th Annual Commencement Exercise Program of the American School of Naturopathy, which includes a statement of the Florida Division, Southern College of Naturopathy, Tampa, and ask you if you can find your name among the faculty there.

A. I don't see my name here. Dr. Ardwelis, he and I were closely associated for three years; Dr. Dayton—.

Q. Do you find the name of N. A. Gilbert on that list at any place?

A. No, it does not seem to be there.

Q. Can you state who signed your diploma from the Southern School of Naturopathy?

A. Well, there was Dr. Cole and Dr. Gilbert, and I believe Dr. Ardwelis, I am not sure.

Q. Did you physically attend the school you refer to as the Northern University?

A. Yes, I did.

Q. What year?

A. Well, I don't recall that.

Q. Where was that school located?

A. The school, itself, was located in Red Bank, New Jersey.

Q. Was it a correspondence school or a school with students?

A. It was a school with students.

Q. What was the name of the president or the Dean of that school?

A. I don't recall his name, but I have it on my records.

Q. Didn't you state at the hearing held at the Atlanta station in December, 1945, that you did not hold an M. D. degree?

A. Not to my recollection.

Q. What degree was conferred upon you by the Northern University?

A. Doctor of Medicine.

Q. When and where did you pass a Civil Service Examination??

A. That was in Bridgeport, Connecticut shortly after the first World War.

Q. Do you remember the year that you got that degree from the Northern University?

A. No, I don't; but I can easy give it to you.

Q. I wish you would.

A. All right.

Q. Was your attendance at each of these institutions full time or part time?

A. It was part time.

Q. At what school?

A. At the Northern.

Q. And you don't recall the years?

A. No, but it is on my credentials.

Q. What correspondence course in electricity did you take?

A. Electrical engineering.

Q. What school?

A. American.

Q. Is that located in Chicago, Ill?

A. Yes.

Q. Did you register under the name of Fritz Urbuteit?

A. Yes.

Q. Did you complete the course?

A. No, I didn't.

Q. Is it a fact that you completed one-third of the course?

A. I think I did more than that.

Q. Is it true that you had only fundamentals of mathematics, the elements of electricity, physics and chemistry at that course?

A. Well, that is a rather vague question there.

Q. In what states do you hold a license to practice Naturopathy?

A. Florida.

Q. Did you ever hold a license to practice in the State of Connecticut?

A. No.

Q. In any other state?

A. No.

Q. When and where did you graduate from high school?

A. I took private tutorship through high school by Dr. Butzitser, professor of surgery.

Q. You never attended a public school, or a parochial school?

A. Yes, I attended Bridgeport High School.

Q. In what year?

A. I don't recall. 1916, 1917, thereabouts.

Q. Did you ever teach psychology?

A. Yes.

Q. When and where did you teach?

A. I taught that in the Southern College.

Q. Of Naturopathy?

A. Yes. I taught that in a private school of my own and I teach it now in the Sinuothermic Institute.

Q. What is the lenght of your total college attendance?

A. Oh, approximately ten years, I would say.

Q. When did you commence to practice Naturopathy in Florida?

A. In 1926.

Q. Where?

A. You mean the address?

Q. Yes.

A. 300 and something Cypress, which was later changed to 13th St., and the number now at the same place is 8106 Thirteenth Street, in Sulfur Springs, a suburb of Tampa.

Q. Have you ever taken any post-graduate work?

A. I take a post-graduate course every year.

Q. When was the first time you had post-graduate work?

A. I wouldn't say—I don't remember—I've been taking it right along.

Q. Have you ever taken any clinical courses?

A. Yes, I take those regularly.

Q. When was the first time you had a clinical course?

A. That I could not say, definitely.

Q. Was that before or after you obtained permission to practice in Florida?

A. Since I have been practicing in Florida.

Q. You never had either post-graduate work or clinical work before you started practicing in Florida?

A. Only in college.

Q. Didn't you obtain your license to practice Naturopathy in Florida upon your representations to the Examining Board that you attended eight years of college, of which three was as a teacher of psychology; that you practiced in Tampa for seven years prior to your application for a license; and took a post-graduate course in surgical medicine under Dr. Butzitser in 1905; and took a two-year clinical course at the Crest Medical Clinic, at Bridgeport, Conn.; and had a total of fifteen years' practice in Florida and Connecticut prior to your filing application for license?

A. No. That is not in the application that I know of. That is not a requisite to an application, that I know of.

Q. You deny making those representations?

A. I don't deny it. I probably did, if you have records of it.

Q. I ask you whether you admit, or deny it.

A. I don't remember. I don't remember what the application consisted of; but whatever is on there is right.

Q. Where did you live in 1923?

A. 8106 Thirteenth Street.

Q. Did you ever live at 361 South Spring Street, Tampa, Florida?

A. No, not that I remember of.

Q. Did you ever live at 527 East Green Street, Tampa, Florida?

A. No.

Q. When you enrolled for your correspondence course in the American Schools did you not give your occupation as a painter, employed by the Ives Manufacturing Co., Bridgeport, Conn., in the application dated October 27, 1916; a carriage painter?

A. I don't remember if I used the term "carriage painter". My position in the Ives Co. was not a carriage painter. My position was an experimenter and foreman.

Q. You were not a painter?

A. No.

Q. In 1923, under the name of Fred Urbuteit, were you employed as a painter by Blue Ribbon Auto Painting Co., 1216 Grand Central Avenue, Tampa?

A. No, I was not employed. I owned it and had others running it.

Q. In 1924 were you not living at 527 East Green Street, and employed as a painter?

A. No, I was not.

Q. I show you the 1923 City Directory for the City of Tampa, Florida, and ask you if you are the Fred Urbuteit, wife Gladys, listed with the Blue Ribbon Auto Painting Co., home, 361 South Spring Street, Sulfur Springs.

A. That may have been "Spring" instead of "Cypress" that I just quoted, and it was changed to Thirteenth Street. That is my name but I wasn't there as a painter. I owned that place.

Mr. Goodrich:

I would like to offer in evidence this page of the City Directory. This is an old City Directory which we had trouble getting.

The Court:

He admits it. Instead of being a painter, he owns it.

(Same is filed in evidence and marked U. S. Exhibit No. 21.)

Q. I show you City Directory for the City of Tampa, Florida, for 1924 and ask you if you are the Fred Urbuteit, wife Gladys, listed there as a painter, with residence at 527 Green Street.

A. That can't be me because I never lived on Green Street.

Q. That is the same address as the other, as given in a previous book.

A. That can't be mine, because I never lived on that street.

Q. You were not a painter in that year?

A. I was never a painter in any sense.

Q. I show you for the year 1925, the City Directory of Tampa and ask you if you are the Fred Urbuteit, wife Gladys, physician, at 527 E. Green Street, Sulfur Springs, listed there.

A. I don't know where that Green Street is. I never recall living on Green Street.

Mr. Pemberton::

I think there was a change of streets out there and I think that is where this comes in.

A. I lived at that same address for nearly twenty-five years and Green Street runs East and West and I was on the street running North and South.

Q. Is it admitted then that these listings I show you are your own listings?

A. That is my name, but not my address.

Mr. Goodrich:

I would like to offer in evidence the last two pages which I have shown here, and ask leave to substitute photostatic copies therefor.

(There being no objections same are filed in evidence and marked U. S. Exhibits Nos. 22 and 23, respectively.)

By Mr. Knight:

Q. Mr. Urbuteit, with reference to the patients whom you have here as witnesses today, was your examination and diagnosis of their condition by Sinuothermic?

A. Well, I used any method that was the most convenient and the most definite. I used Sinuothermic mostly for examination; yes.

Q. That was the basis of your examination?

A. Correct.

Mr. Goodrich:

No further questions on his qualifications.

Mr. Knight:

I would like to argue this witness' qualifications.

Mr. Pemberton:

My purpose was to interrogate Dr. Urbuteit with reference to those witnesses.

The Court:

You can't go into that diagnosis until you get a witness on the stand. If you want to put a diagnosis in the record before you call your witness you may do that.

Mr. Pemberton:

That is what I propose to do.

A. This Mrs. Porter here is diagnosed as a cancer—.

Mr. Knight:

Object to this witness stating any diagnosis, because; first, he is not qualified. It affirmatively appears that

the diagnosis was made by the Sinuothermic machine and there is evidence in this record that shows this unreliable. Any diagnosis made by this machine would not be admissible in evidence because there is no contradicted evidence in the record that the machine cannot be used for diagnosis, and it is unreliable in all its readings and variable in its readings, and the meters, themselves, are unreliable; and any diagnosis made apart from the machine would not be admissible in evidence on the question before the Court, which relates solely to the machine.

The Court:

I can only decide this case from the testimony; and under the evidence in this case the testimony of Dr. Urbuteit as to diagnosis, using those machines, would not be admissible, and therefore the objection is sustained.

178 MRS. J. W. PORTER was called as a witness on behalf of the defendant, and, being first duly sworn, testified as follows:

Direct Examination.

By Mr. Pemberton:

Q. State your name and address.

A. Mrs. J. W. Porter; 215 W. Columbus Drive. Now when I went to him—.

Q. What is your present address?

A. That's where, 215 W. Columbus Drive.

Q. What city?

A. Tampa.

Q. Florida?

A. Yes.

Q. How old are you?
A. Seventy-eight.
Q. Are you acquainted with Dr. Urbuteit?
A. Yes.
Q. Did you ever take treatments from him with the Sinuothermic machine?
A. Yes.
Q. When was that?
A. It has been about nine years ago.
Q. How long did you take treatments from him?
A. Seven weeks.
Q. What was your condition when you went to him?
A. Very bad.

Mr. Knight:
The Government objects. She is not capable as a lay witness of testifying as to her physical condition or any ailments with which she may have suffered. There is no proper foundation laid.

The Court:
Objection sustained.

Mr. Pemberton:
There is no other way to disclose that testimony by a man outside of the medical profession, unless he has enough money to buy it.

The Court:
I think that remark is very uncalled for, especially by a member of this Bar.

Mr. Pemberton:
When I say "buy it", I don't mean that their testimony would be bought in the sense it would be bought —I mean the ability to pay for it, unlike the Government.

The Court:

That does not change the rule of evidence before this Court or the law upon which this case is based. I don't care to hear any more argument along that line. In the first place, there must be a diagnosis by one competent to diagnose under the law. Second, you can't go into a Courtroom and testify that a physician told you that you had a disease. It is hearsay. A person cannot go on the witness stand and testify that they have a disease, because they don't know that; that is only guess work. That can come only from a medical man, not a layman. If you had a physician here who was competent to diagnose, then it would be a different thing. I don't say that Dr. Urbuteit is not competent to diagnose, but I do say that the testimony before this Court is that that machine will not diagnose and that that is the basis of his diagnosis; and there is no testimony before this Court to the contrary. Now, I am not judging of the qualifications of Dr. Urbuteit, but if Dr. Urbuteit diagnosed this lady's disease in some other way than by that machine, then this Court is not concerned with it.

Mr. Pemberton:

The point there would be it is the treatment. Not only diagnosis, but the treatment. The diagnosis might have been made otherwise.

The Court:

You can't get around the fact that your own witness has stated that the basis of his diagnosis was that machine; and I am satisfied he didn't perjure himself. Objection sustained.

Mr. Pemberton:

Under the circumstances, there is no use taking up the time of the Court to bring these people in and offer them, but I would like the record to show that we are prepared to offer approximately thirty witnesses who had been treated by Dr. Urbuteit. So that without the necessity of—.

The Court:

State that in the record.

Mr. Pemberton:

The Claimant, Dr. Fred Urbuteit, hereby offers to present in evidence approximately thirty witnesses who have been treated by Dr. Fred Urbuteit with the Sinuothermic machine, said witnesses to testify to their condition as known to them when they went to Dr. Urbuteit for treatment, as to the treatment received by them, and their condition during and after the treatments, and at the present time. Claimant further offers to testify as to his diagnosis with the use of the Sinuothermic machine, and otherwise, with reference to the persons whose testimony as to their treatment would be offered, and to testify as to his treatment of such persons and the results obtained from such treatments.

Mr. Knight:

To which proffers, and each of them, severally, the Government objects, because: First, it appears by the testimony of the witness Urbuteit that the basis of his diagnosis was the Sinuothermic machine; and it appears by the uncontradicted testimony in this case that the Sinuothermic machine and the meters used in the diagnosis are inaccurate, incapable of specific measurements and that the readings vary with all external conditions. Second, that no proper foundation has been laid for such

testimony. Third, that the testimony proffered does not bear or tend to bear upon any of the specific issues made in this case. Fourth, that as to the lay witnesses, it would call for an opinion which they are not qualified to give; or, in the alternate, for a hearsay statement as to the opinion of some physician who is not produced as a witness.

The Court:

Objection sustained. The Court finds for the Government. The United States Attorneys will prepare an appropriate decree and present the same to the Court.

(Thereupon, Court adjourned.)

On the 27th day of January, 1947, Findings of Fact and Conclusions of Law were filed in the following words, to-wit:

On the basis of the evidence of record in the above entitled cause the following findings of fact and conclusions of law are made:

185 FINDINGS OF FACT.

1.

The devices were manufactured at Tampa, Florida. On July 25, 1945; August 14, 1945; August 18, 1945; and September 21, 1945, they were shipped from Tampa, Florida, to Cincinnati, Ohio, to be used in the diagnosis, cure, mitigation, treatment, and prevention of disease and to be leased and sold to the public for those purposes.

The leaflets entitled "The Road to Health" accompanied the devices while in interstate commerce and both the said machines and the leaflets were seized in the possession of the original consignee in Cincinnati, Ohio.

2.

The leaflet entitled "The Road to Health" contains many claims for the devices.

3.

There are two externally different types of electrical device involved, the so-called master unit and the so-called treating unit. The master unit consists of a wooden cabinet containing electrical parts including three voltmeters, a milliamperemeter, a light switch, a potentiometer, a step-down transformer, wires, and pad electrodes which are pieces of flat metal padded with wool felt on one side and sheet rubber on the other. The electrodes are oval in shape and approximately 3½ x 4½ inches in size. The treating unit consists of a wooden box containing the same electrical parts except for the four meters. The electrodes are intended to be applied to the area of the body in which pain exists, and the current is passed through the body by turning the potentiometer control, increasing or decreasing this control to give a tingling sensation. These machines do not alter the form of the electrical current delivered from the ordinary wall socket to any other form of current. They step the voltage down to a maximum value of 60 volts. The only electrical effect of either of the devices is one of electric stimulation.

4.

The leaflets entitled "The Road to Health" consists of a reproduction of testimonials and recitations of claimed diagnostic values and therapeutic effects of the device. It represents that the articles are effective in the diagnosis, cure, mitigation, treatment, and prevention of appendicitis, arthritis, cancer (internal, of the brain, and external), deficient hearing, diabetes, glandular disorders, hardening of the arteries, hay fever, heart disease, infantile paralysis, internal growths, kidney disease, low blood pressure, menstrual dysfunction or discomfort associated with menstruation, nervousness and nerve disorders, obstructed colon, paralysis, painful breathing, peritonitis, prostate trouble, tuberculosis, tumors of the bladder and uterus, ulcerated colon, and uterine hemorrhage.

5.

It is asserted in the labeling that the machine will register the exact nature of any disease. The undisputed evidence produced by well qualified expert witnesses shows that the voltmeters and millamperemeter readings are efffected by the resistance of the body to electrical current. The major part of the resistance is in the skin and the resistance to electrical current varies according to the condition of the skin in regard to moisture, cleanliness, pressure exerted on the electrodes, and other factors. Resistance of different persons varies and the resistance of the same person varies from time to time. The voltmeters and the milliamperemeter are not well adapted for use in reading minor changes in body resistance to electrical current and they are not accurate at less than 20% of their full scale, which for the milliamperemeter is 20 milliamperes. It is not considered

safe to pass any current of more than 20 milliamperes through the human body. It is not possible to correlate body resistance to electric current with pathological changes in the body and internally the current is conducted thru body fluids and not body tissues. The master machine, therefore, is incapable of diagnosing any diseased condition.

6.

There are many claims of therapeutic and curative effect. These claims are based upon the premise that the instrument will produce a flow of electricity through the affected tissue and in some unexplained manner cause a return to health. The evidence is overwhelming that no such effect is or can be produced by this device. The claims are, therefore, false and misleading and cannot be and are not substantiated.

7.

It is impractical and unnecessary to enumerate all of the claims and all of the inaccuracies. The findings at this stage will be confined to the general statement heretofore made of the underlying principles upon which the claimed beneficial results are said to be possible of attainment and the further statement of the evidentiary showing of the impossibility of the principles being put to practical application with these instruments.

8.

The devices in question were found and seized together with their accompanying labeling in Cincinnati, Ohio.

188 CONCLUSIONS OF LAW.

The following conclusions of law are made:

1.

The Court has jurisdiction of the parties and the subject matter of this action under the provisions of the Federal Food, Drug, and Cosmetic Act.

2.

The devices were shipped in interstate commerce within the meaning of that Act.

3.

The devices were misbranded within the meaning of that term as defined by the Act.

4.

The Government is entitled to an order directing the destruction pursuant to the provisions of the Act of the devices in question upon the showing that and for the reason that the devices shipped in interstate commerce were misbranded.

(Sgd.) AUGUSTINE V. LONG,
United States District Judge.

Dated at Gainesville, Florida, this 27th day of January, 1947.

On the 27th day of January, 1947, Decree of Condemnation was filed by the Court in the following words, to-wit:

DECREE OF CONDEMNATION.

On January 9, 1947, a second amended libel of information against the above described articles of device was filed in this Court on behalf of the United States of America by the United States Attorney and the Assistant United States Attorney for this district. The amended libel alleges that the articles proceeded against are devices which were shipped in interstate commerce and are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (21 USC 352(a)). Pursuant to motion the United States Marshal for the Southern District of Ohio therefore had seized the said articles on September 28, 1945 and October 2, 1945. Fred Urbeteit of Tampa, Florida, and J. J. H. Kelsch of Cincinnati, Ohio, intervened and filed claim to said articles. The case being at issue came on to be heard before this Court on January 23, 1947, and the Court having heard the evidence adduced on behalf of the Government and on behalf of the Claimants;

The Court being fully advised in the premises, it is

Ordered, Adjudged, and Decreed that the said articles under seizure are misbranded in violation of 21 U. S. C. 352(a), and are therefore hereby condemned pursuant to 21 U. S. C. 334(a); and it is further

Ordered, Adjudged, and Decreed that the United States Marshal for the Southern District of Ohio shall destroy the said articles of device and the labeling accompanying

them, provided however that the said United States Marshal may sell or otherwise dispose of any salvageable disposition into the Treasury of the United States; and it is further

Ordered, Adjudged and Decreed pursuant to 21 U. S. C. 334(e) that the United States of America shall recover from said claimants, Fred Urbeteit and J. J. H. Kelsch, costs, fees, and proper expenses in this matter incurred and to be hereinafter taxed, and the Court retains jurisdiction herein to tax the same and enter judgment therefor.

Done and Ordered at Gainesville, Florida, this 27th day of January, A. D. 1947.

(Sgd.) AUGUSTINE V. LONG,
United States District Judge.

On the 4th day of February, 1947, Motion for New Trial was filed by the defendant in the following words, to-wit:

189 MOTION FOR NEW TRIAL.

Comes now the claimant. Fred Urbeteit, and moves the Court to set aside and vacate the Judgment entered herein on the 27th day of January, 1947, and for a new trial, on the following grounds:

1. There was no substantial evidence to sustain the said judgment.

2. The said judgment is contrary to law.

3. The Court erred in overruling Claimants objections to the evidence.

4. The Court erred in sustaining Libelant's objections to evidence offered by Claimant and excluded on Libelant's objections.

(Sgd.) H. O. PEMBERTON,
(H. O. Pemberton),
Attorney for Claimant.

Tallahassee, Florida.

On the 6th day of February, 1947, Order Denying Motion for New Trial was entered by the Court in the following words, to-wit:

This cause coming on to be heard upon motion for a new trial filed by the claimant, Fred Urbeteit, and the Court being of the opinion that the trial was without error, and that the judgment of the Court is correct, it is considered by the Court and so ordered that said motion for a new trial be and the same is denied.

Done and Ordered this 6th day of February, A. D. 1947.

(Sgd.) AUGUSTINE V. LONG,
District Judge.

On the 22nd day of April, 1947, MOTION FOR TAXATION OF AND JUDGMENT AS TO COSTS was filed by the Court in the following words, to-wit:

191 (Title Omitted.)

Comes now the libelant, the United States of America, by its undersigned attorneys, and pursuant to the order

of this Court contained in the decree of condemnation entered on 27 January, 1947, shows unto the Court that, in accordance with the attached affidavit and statements, the following costs, fees, and expenses incident and necessary to the preparation and prosecution of this suit have been incurred and/or paid by the libelant:

(1)	Fees of Clerk of United States District Court for the Southern District of Ohio, Western Division, Cincinnati, Ohio, prior to transfer of cause to United States District Court for the Northern District of Florida, Gainesville Division	$ 15.00
(2)	Fees and expenses of United States Marshal for the Southern District of Ohio, Western Division, Cincinnati, Ohio	19.39
(3)	Long distant telephone expense incurred by Food and Drug Administration officers, the cost emanating from or received at Gainesville, Florida betwen 16 January and 24 January, 1947	9.20
(4)	Transportation expenses, pullman fares, per diem expenses, conference fees, and witness fees of eight expert witnesses necessary and incident to preparation of cause for trial .	554.20
(5)	Transportation expenses, pullman fares, per diem of four Food and Drug Administration inspectors	286.21
(6)	Fee of Clerk of United States District Court for the Northern District of Florida, Gainesville Division	15.00

(7)	Docket fee of United States Attorney for the Northern District of Florida, Gainesville Division	10.00
(8)	Disbursements by the United States Marshal for the Northern District of Florida on account of four witnesses' fees and expenses	440.10
	Total	$1,349.10

Wherefore, plaintiff moves that the foregoing items of expenses, costs and fees be approved and taxed as proper costs, fees, and expenses herein and on account hereof, and that a judgment therefor be entered in favor of the plaintiff and against the claimants, Fred Urbeteit and J. J. H. Kelsch on account thereof.

GEORGE EARL HOFFMAN,
United States Attorney.
HAYFORD O. ENWALL,
Assistant United States Attorney.

On the 22nd day of April, 1947, Judgment Taxing Costs was filed by the Court in the following words, to-wit:

193 JUDGMENT TAXING COSTS.

This matter coming on to be heard further before me this day ex parte upon motion of the plaintiff for the order and judgment of this Court taxing the costs herein to be allowed unto the plaintiff, and the Court being fully advised of its order to be entered in the premises, it is therefore hereby

Ordered that all of the items set forth in the plaintiff's motion, the affidavit and statements attached thereto on account of the costs, fees and expenses incident to the prosecution of this suit, save and except the long distant telephone expense in the sum of Nine and 20/100 Dollars ($9.20), and the transportation expenses, pullman fares, and per diem of the Food and Drug Inspectors, S. W. Ahlmann, C. S. McKellogg, and Herbert McLeod, aggregating One Hundred Eighty Nine and 26/100 Dollars ($189.26), be and the same are approved hereby as proper and allowable items of costs; it being hereby further

Ordered and Adjudged that the plaintiff, United States of America, do have and recover of and from the claimants, Fred Urbeteit and J. J. H. Kelsch on account of said approved costs, fees and expenses, the aggregate total sum of Eleven Hundred and Fifty and 64/100 Dollars ($1150.64), together with such further and other costs as may hereafter accrue, for which let execution issue.

Done, Ordered and Adjudged this 21st day of April, A. D. 1947.

(Sgd.) AUGUSTINE V. LONG,
United States District Judge.

194 On the 1st day of May, 1947, NOTICE OF APPEAL TO THE CIRCUIT COURT OF APPEALS was filed by Defendant in the following words, to-wit:

In the District Court of the United States for the Northern District of Florida, Gainesville Division.

Gainesville Civil No. 73.

F. D. C. No. 17606.

The United States of America

vs.

16 Articles of Device, more or less, labeled in part "Sinuothermic" including a number of leaflets relating thereto entitled "The Road to Health."

Notice is hereby given that the Claimant, Fred Urbuteit, hereby appeals to the Circuit Court of Appeals for the Fifth Circuit from the order of the District Court entered in this cause on the 27th day of January, 1937, and the order of the District Court dated the 6th day of February, 1947, and entered in this cause on said date, denying the motion for a new trial herein.

(Sgd.) H. O. PEMBERTON,
(H. O. Pemberton),
Attorney for the Claimant,
Fred Urbuteit.

Address: Tallahassee, Florida.

195 On the 6th day of June, 1947, DESIGNATION OF CONTENTS OF RECORD ON APPEAL was filed by Defendant in the following words, to-wit:

(Title Omitted.)

Appellant designates the following portions of the record, proceedings and evidence to be contained in the record on appeal.

1. The amended libel filed by plaintiff October 2, 1945.

2. Claim of Fred Urbuteit filed October 29, 1945.

3. Certified copy of order transferring libel to Northern District of Florida.

4. Second Amended Libel filed January 9, 1947.

5. Consent to amendment and claim of Fred Urbuteit and J. J. H. Kelsch filed December 10, 1946.

6. Court Reporter's transcript of proceedings filed February 20, 1947.

7. Findings of Fact and Conclusions of law by Judge A. V. Long filed January 27, 1947.

8. Final decree filed January 27, 1947.

9. Motion for New Trial filed by Claimant Fred Urbuteit February 4, 1947.

10. Order denying Motion for New Trial filed February 6, 1947.

11. Motion for taxation of and judgment as to costs filed April 22, 1947.

12. Notice of Appeal to Circuit Court of Appeals by Fred Urbuteit filed May 1, 1947.

13. This designation.

14. Statement of the points on which Appellant intends to rely on appeal.

H. O. PEMBERTON,
(H. O. Pemberton),
Attorney for Appellant.

Tallahassee, Florida.

Appellant states the points on which he intends to rely on the appeal as follows:

1. The Court erred in overruling Claimant's objections to evidence.

2. The Court erred in sustaining Libelant's objections to evidence.

3. The Court erred in entering a judgment in favor of Libelant.

4. The Court erred in denying Claimant's Motion for a New Trial.

H. O. PEMBERTON,
(H. O. Pemberton),
Attorney for Appellant.

Tallahassee, Florida.

A copy of the foregoing designation and statement of points to be relied upon by Appellant was received by me this 6th day of June, 1947.

(Sgd.) HAYFORD O. ENWALL,
Assistant United States District Attorney.

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197 On the 6th day of June, 1947, an ORDER was entered by the Court extending time for filing Transcript of Record on Appeal in the following words, to-wit:

This cause coming on to be heard upon application of the defendant for thirty additional days in which to file transcript of record on appeal with the Clerk of the U. S. Circuit Court of Appeals, and the Court being fully advised in the premises, it is

Ordered that the defendant be allowed thirty days from the date of this order in which to prepare and file transcript of Record on Appeal.

Done and Ordered at Gainesville, Florida this 6th day of June, A. D. 1947.

(Sgd.) AUGUSTINE V. LONG,
District Judge.

United States of America,
Northern District of Florida.

I, WM. LOGAN HILL, Clerk of the United States District Court for the Northern District of Florida, do hereby certify that the foregoing pages, numbered one to One Hundred Ninety-seven, constitute a true and correct transcript of the record as set forth in Designation of Contents of Record on Appeal in the case of United States of America versus 16 Articles of Device, More or Less, Labeled "Sinuothermic" and a Number of Leaflets Entitled "The Road to Health", Gainesville Civil Action No. 73, wherein the Claimant, Fred Urbeteit, is prosecuting an appeal to the United States Circuit Court of Appeals for the Fifth District.

Witness My Hand and the Seal of Said Court at Pensacola in the Northern District of Florida, this 18th day of June, A. D. 1947.

WM. LOGAN HILL,
Clerk, U. S. District Court,
Northern District of Florida.

(Seal)

That thereafter the following proceedings were had in said cause in the United States Circuit Court of Appeals for the Fifth Circuit, viz:

Argument and submission

Extract from the Minutes of October 22, 1947

No. 12033

FRED URBETZIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC.

versus

UNITED STATES OF AMERICA

On this day this cause was called, and, after argument by Hollis O. Pemberton, Esq., for appellant, and John T. Grigsby, Esq., Attorney, Department of Justice, for appellee, was submitted to the Court.

Opinion of the Court filed

November 7, 1947

In the United States Circuit Court of Appeals for the Fifth Circuit

No. 12033

FRED URBETZIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC., APPELLANT

versus

UNITED STATES OF AMERICA, APPELLEE

Appeal from the District Court of the United States for the Northern District of Florida

(November 7, 1947)

Before SIBLEY, HUTCHESON, and HOLMES, Circuit Judges

SIBLEY, Circuit Judge: Under the Food, Drug and Cosmetics Act of 1938, Section 304 (21 U. S. C. A. § 334), sixteen electrical machines or devices were seized for condemnation in Ohio as having been misbranded when shipped in interstate commerce

from Tampa, Florida, by appellant Fred Urbeteit to J. J. H. Kelsch at Cincinnati. The misbranding was alleged to consist in printed matter which accompanied them while in interstate commerce which was false and misleading in that it represented the machines as having therapeutic value in the diagnosis and treatment of stated diseases of man, whereas the devices were not effective for such purposes. Kelsch claimed six of them as his and Urbeteit claimed ten of them as belonging to himself but rented to Kelsch. After trial, the case by consent having been transferred to Florida, a judgment of condemnation and destruction was rendered, with recovery of some $1,150.64 costs. Urbeteit appeals.

The claims admit that six machines were sold by Urbeteit to Kelsch and shipped in interstate commerce as alleged, and that the ten others were rented and shipped to Kelsch by express, and that the printed matter was at the request of Kelsch sent by Urbeteit to Kelsch by parcel post; but deny that it was a labeling of the machines or accompanied them, and deny that its statements are false and misleading. The testimony, in great volume, related mostly to the falsity of the statements. We consider first, however, whether there was a misbranding proven under the Act.

Section 301 (a) (c) (21 U. S. C. A. § 331 (a) (c)) prohibits the introduction into and the receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and Section 304 (a) (21 U. S. C. A. § 334 (a)) provides for seizure and condemnation of such. It is not denied that these machines were devices within the Act. By Section 502 (a) (21 U. S. C. A. § 352 (a)) a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. A definition in Section 201 (21 U. S. C. A. § 321), which is the dictionary of the Act, is: "(m) The term labeling means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The last three quoted words are critical here. They make the term "labeling" broader than "label" as defined in paragraph (k), which includes only what is "displayed on the immediate container" of an article. How much broader? In *United States* vs *Research Laboratories*, 126 F. (2) 42, it was held that printed matter which did not travel with the article but was sent by the same shipper to the same consignee and received at the same time for use in connection with the article, "accompanied" it. But the same court in *Alberty* vs. *United States*, 159 Fed. (2) 278, refused so to hold when the printed matter and the article were shipped two months apart and not simultaneously. Accepting those decisions as sound, the latter controls here. It is shown that machines valued at $4,300 were shipped July 25, 1945; value

$1,200 August 14; value $800 August 18; and value $1,200 Sept. 21. Kelsch testified that he had an understanding with Urbeteit that he would mail him some printed matter before he finally contracted for the machines, and that the matter was received about September, after the machines were delivered. It was found by the inspectors in Kelsch's consultation room, the machines being all in other rooms, on Sept. 5. The claim alleges the printed matter was mailed Sept. 1. It did not "accompany" in any fair sense either shipment. Both the amended libel and the second amended libel allege that the false leaflets "accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce." This is the exact language of Section 304 (a), the forfeiture provision of the statute, but it is shown not to be true of any shipment. The first three shipments went forward and were received by Kelsch, and put to work in his medical practice several weeks before any leaflets were sent. They did not accompany any of the devices while they were in interstate commerce. The last shipment went forward three weeks behind the leaflets, and was not accompanied by them. Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched.

It may be doubted that the printed matter is in its nature a labeling for the machines. It looks like a small newspaper, entitled "The Road to Health, By Dr. Fred Urbeteit. Every subject pertaining to Health, Doctoring and Nursing is being taught at the College of Sinuothermic Institute, Inc., 307 West Euclid Ave., Tampa, Florida". To the left of this heading is a picture of Dr. Fred Urbeteit, President of Sinuothermic Institute, Inc., and to the right an attractive picture of the Institute and its grounds. Fifteen columns of fine print are below, consisting of testimonials and case histories of patients who had been treated at the Institute by Dr. Urbeteit, with unstinted praise of both. The Sinuothermic machine is mentioned and praised as an instrument of diagnosis and teatment, but there is no description or picture of the machine or any explanation of its operation, or any suggestion that it is for sale. The whole thing appears to be an advertisement for the Institute and Dr. Urbeteit, rather than something to accompany machines. Dr. Urbeteit is licensed as a practitioner of naturopathy in Florida. Dr. Klesch is a chiropractor in Ohio. Dr. Klesch became interested in Dr. Urbeteit's work and took a three weeks course at the Institute, and on the strength of it, on returning to Ohio, bought some of the machines, and rented others. He rerented one to a patient to use at home, and sold one to another patient who moved to another State. The literature apparently was intended to advertise himself as following the methods of Dr. Urbeteit, rather than to explain or sell machines.

Whether we ought to hold it a labeling of these machines if shipped simultaneously with them may be doubted. But if it could be called labeling, it is not proved by the present skimpy evidence that it accompanied the machines or any of them while they were in interstate commerce.

Dr. Urbeteit vigorously contended that all he had said in "The Road to Health" was true. He offered in his claim, since no employee of the United States had any actual knowledge of his machine and only a few practitioners whom he had instructed, to conduct a series of tests of it in cooperation with practitioners of medicine, osteopathy, chiropractic, and naturopathy approved by the court, on persons preferably before treated by medical practitioners without success, they to be examined before and after the test by physicians appointed by the court, during such period as the court should fix, their findings of the results to be evidence in the case. This was not done. Dr. Urbeteit at least seems convinced of the efficacy of his machine. He testifies that he was himself a suffering and distorted victim of arthritis deformans, and was helped to a degree which he described in detail, and exhibited his diseased joints to the court. He describes the construction of his machine, claims peculiarities in the winding of the electrical transformers in it which experimentally he found to produce currents peculiarly affected by diseased or congested bodily tissues, which when measured indicate where the trouble is, although often remote from the pain and other symptoms, and that it aided in locating the cause of trouble; and that a modified type of machine also was useful in treating many ailments. He testified in detail as to each case mentioned in "The Road to Health". He had thirty of his patients present whom he offered as witnesses to the benefits they had received, many of them being those mentioned in "The Road to Health". The judge refused to hear them, on the ground that being laymen they could not testify what was the matter with them and consequently could not say what they were relieved from, and that the diagnoses testified to by Dr. Urbeteit could not be accepted because he rested them on the use of his machine which the Government's witnesses, who were men of high standing in medicine and in the electrical arts, had testified could not do what Dr. Urbeteit claimed. These rulings were error. One was based on the idea that Dr. Urbeteit had made his diagnoses solely on the indications of the machine. But his testimony as a whole was that he used all known methods of diagnosis, that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was, and it was then a matter of judgment as to what the disease was. He only claimed the machine to be an aid in diagnosing. The patients themselves could

certainly know whether their externa[illegible] symptoms abated and their pains ceased. Urbeteit, being a licensed doctor of some twenty years practice, could express expert opinions. The judge might, after hearing all the evidence, prefer the expert opinions of the Government witnesses to those of Dr. Urbeteit, even as against the facts to which he and his witnesses might swear, but he should have heard all the competent testimony before making up his mind. The most eminent physicians and scientists have in the past erred in their opinions, and opinions generally must yield to well proven contrary facts. The case ought to have been more fully tried.

The judgment is reversed and the cause remanded for further proceedings consistent with this opinion.

Judgment

Extract from the Minutes of November 7, 1947

No. 12033

FRED UBRETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC", ETC.

versus

UNITED STATES OF AMERICA

This cause came on to be heard on the transcript of the record from the District Court of the United States for the Northern District of Florida, and was argued by counsel;

On consideration whereof, It is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be, and the same is hereby, reversed; and that this cause be, and it is hereby, remanded to the said District Court for further proceedings consistent with the opinion of this court.

Clerk's certificate

UNITED STATES OF AMERICA,

United States Circuit Court of Appeals, Fifth Circuit

I, Oakley F. Dodd, Clerk of the United States Circuit Court of Appeals for the Fifth Circuit, do hereby certify that the pages numbered from 179 to 187 next preceding this certificate contain full, true and complete copies of all the pleadings, record entries and proceedings, including the opinion of the United States Circuit Court of Appeals for the Fifth Circuit, in a certain cause in said Court, numbered 12033, wherein Fred Urbeteit, Claimant of 16 Articles of Device, more or less, labeled "Sinuothermic", etc.,

is appellant, and United States of America, is appellee, as full, true, and complete as the originals of the same now remain in my office.

I further certify that the pages of the printed record numbered from 1 to 178 are identical with the printed record upon which said cause was heard and decided in the said Circuit Court of Appeals.

In testimony whereof, I hereunto subscribe my name and affix the seal of the said United States Circuit Court of Appeals, at my office in the City of New Orleans, Louisiana, in the Fifth Circuit, this 13th day of January, A. D. 1948.

[SEAL] (S.) OAKLEY E. DODD,
Clerk of the United States Circuit Court of Appeals, Fifth Circuit.

U. S. GOVERNMENT PRINTING OFFICE: 1948

Supreme Court of the United States

Order allowing certiorari

Filed April 19, 1948

The petition herein for a writ of certiorari to the United States Circuit Court of Appeals for the Fifth Circuit is granted, and the case is transferred to the summary.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

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In the Supreme Court of the United States

OCTOBER TERM, 1947

No. 577

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE MORE OR LESS, LABELED "SINUOTHERMIC," ETC.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

The Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the United States Circuit Court of Appeals for the Fifth Circuit, reversing the judgment of the District Court of the United States for the Northern District of Florida condemning certain devices as misbranded under Section 304 of the Federal Food, Drug, and Cosmetic Act.

OPINION BELOW

The opinion of the circuit court of appeals (R. 179–183) is reported in 164 F. 2d 245.

JURISDICTION

The judgment of the circuit court of appeals was entered November 7, 1947 (R. 183). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1945.

QUESTIONS PRESENTED

1. Whether leaflets claiming diagnostic capabilities and therapeutic values for machines transported in interstate commerce could be considered as printed or graphic matter "accompanying" the machines, and thus constituted "labeling" within the meaning of Section 201 (m) of the Federal Food, Drug, and Cosmetic Act, where the leaflets were shipped separately from the machines but were supplied by the shipper to the consignee for the purpose of explaining to purchasers and renters of the machines, and prospective patients, the usefulness of the machines.

2. Whether printed and graphic matter shipped to explain the uses to be made of the machines, which information was given nowhere else in the labeling, constitutes "labeling" within the meaning of the Act even though it may also constitute advertising.

3. Whether the Government was entitled to a decree of condemnation because of false claims of diagnostic capabilities despite alleged errors in exclusion of evidence offered to show the claimed therapeutic values of the machines.

STATUTE INVOLVED

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), provides in pertinent part:

> SEC. 201. For the purposes of this Act—
>
> * * * * *
>
> (h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; * * *
>
> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
>
> SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *
>
> SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

STATEMENT

On January 9, 1947, a second amended libel of information was filed in the United States District Court for the Northern District of Florida, under Section 304 of the Federal Food, Drug, and Cosmetic Act, seeking the seizure and condemnation of 16 "articles of device" labeled "Sinuothermic" (R. 11–15). The libel alleged that the device was misbranded within the meaning of Section 502 (a) when introduced into and while in interstate commerce in that representations made in a leaflet entitled "The Road to Health," relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment, and prevention of disease, were false and misleading. It was charged that the leaflet had accompanied the device in interstate commerce (R. 13).

Fred Urbeteit, the respondent, who is a naturopathic physician (R. 119), appeared as claimant of ten of the devices of the so-called treating unit type (R. 5, 12, 10), and J. J. H. Kelsch, an unlicensed naturopathic and chiropractic physician (R. 32), appeared as claimant of the remainder of the devices, two of which were the so-called master units and four of which were of the treating unit type (R. 5, 12, 10). Together they filed a "consent to amendment and claim" which admitted factual recitals in previous pleadings, renewed the statements of ownership, ad-

mitted that the devices and leaflets had been shipped in interstate commerce, but denied that they were shipped together or that they related to each other, and neither admitted nor denied the dates of the shipments because of lack of exact knowledge. They also denied that the leaflets accompanied the devices in interstate commerce and that the representations made in the leaflets were false or misleading (R. 10–11, 11–15).

The case was tried to the court without a jury (R. 15). The claimants' answer admitted that the sixteen devices and a number of leaflets, entitled "The Road to Health," were introduced into interstate commerce at Tampa, Florida, for shipment to Cincinnati, Ohio, and were in possession of Kelsch at Cincinnati when the libel was filed (R. 10, 13–14). The evidence showed that the respondent was the shipper (R. 24, 29–31). Four shipments of the devices were made by means of the facilities of the Railway Express Agency, the first on July 25, 1945, the second on August 14, 1945, the third on August 18, 1945, and the fourth on September 21, 1945 (R. 24–25).

Kelsch testified that he had received a course of instruction from the respondent in Florida some time in June 1945, and that he had remained there approximately three weeks (R. 25–26). While there, arrangements were made for the purchase of some devices and for the rental of others, contingent upon Kelsch's ability to make financial arrangements in Cincinnati (R. 29).

As a part of the same transaction, respondent agreed to supply a quantity of the leaflets, "The Road to Health," for the purpose of explaining the machines to Kelsch's patients (R. 29). Accordingly, the leaflets were shipped to Kelsch in bulk supply and received by him. Pursuant to an understanding between Kelsch and respondent, some of the leaflets were mailed out to patients and others were shown to patients during consultation (R. 29-30).

Kelsch first testified that he received the leaflets, by parcel post, after the machines were shipped to him (R. 29, 6), but on closer examination it appeared that he did not know the exact date the leaflets were received. He stated that they were received sometime around September (R. 31). Some of the leaflets were found on September 5, 1945, in and on a desk in Kelsch's main consulting room within the reach and view of patients who consulted with him there. The devices were in the adjoining consulting rooms and treating rooms. The devices bore a label which contained the statement "U. S. Patent Sinuothermic Trade Mark" together with a serial number (R. 20), and no other labeling except for "The Road to Health" was delivered to the consignee.

In addition to many representations of therapeutic value involving, among many others (see R. 165), such varigated diseases as cancer, tuberculosis, diabetes, appendicitis, heart disease, hay

fever, infantile paralysis, menstrual discomfort, peritonitis, and nervousness, the leaflet, "The Road to Health," in part describes the diagnostic capabilities of the machines as follows:

IMPORTANCE OF EXAMINATION

You must realize the all importance of being examined the Sinuothermic way, which leaves out all guess work as Sinuothermic locates the cause and registers exactly [p. 1, col. 3].

* * * * *

CANCER DANGER SIGNAL

* * * At the Sinuothermic Institute no one is ever treated without first being thoroughly examined, and it should be remembered that NO really COMPETENT doctor will treat a condition that might be a cancer without first making a careful examination. INSIST on a thorough examination no matter who your doctor is. Be examined with Sinuothermic which registers exactly and never makes a mistake [p. 1, col. 4].

* * * * *

BE EXAMINED

Why have someone guess *at what your ailment is* when at the Sinuothermic Institute, Inc., you can be examined with that never failing Sinuothermic machine which leaves out all guess work and registers exactly [p. 1, col. 4]. [Italics added.]

* * * * *

SINUOTHERMIC EXAMINATION

> Dr. Urbuteit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but she was also pregnant about 5 months * * * [p. 2, col. 6].
>
> * * * * *

SCIENCE AT ITS PEAK

> Sinuothermic is the last word in scientific discoveries. Sinuothermic is a tester of human tissue. You could liken Sinuothermic to the tester they use to test your radio tubes with * * * Sinuothermic registers exactly the condition of human tissue [p. 2, col. 6].

There are many other representations in the leaflet[1] which represent that the machine is capable of locating the cause of any ailment and registering exactly.

The evidence at the trial disclosed that the Sinuothermic machine is designed to draw electricity from an ordinary household wall socket, to control the full line voltage (electrical pressure) by turning in variable amounts from zero to the full line voltage (115–120 volts), to step this voltage down to a maximum value of 60 volts, and to deliver current to the patient so as to flow

[1] This exhibit (R. 13, 19), which was before the Circuit Court of Appearls, is on file with the Clerk of this Court.

through the body between two pad electrodes that are applied to the bare skin (R. 39–44, 50–52, 164). The small machines differed from the master units only in the omission of the four indicating meters (R. 43, 164).

The Government's evidence showed that even the master model which had four indicating meters, was incapable of registering any pathological changes in the body. This because the meters were primarily affected by the patient's resistance to electrical current and because internally the current is conducted through body fluids and not body tissues (R. 43, 51–52). The so-called treating units did not have the four indicating meters (R. 43). The expert testimony for the Government was that these machines were without value in the diagnosis of the disease conditions involved (R. 72, 76, 79–80, 83–85, 88–89, 91, 93, 96–97, 99, 100, 104–105, 109–112).

Urbeteit undertook a description of his method of diagnosis at the trial (R. 126–127, 128–130). He said that when the current from the machine encounters a lesion in the human body the meters will register "the amount of intensity or resistance there is in that particular area" (R. 127, 128–129). He then stated, however, that:

> *The meters do not tell me what the ailment is,* it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of ob-

> struction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is * * * R. 129.
>
> * * * * *
>
> * * * There is no way of registering the kind of ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever that something is wrong it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. *But I find in all my experience it is not necessary to go to all that trouble to take those tests.* As long as the patient gets well, that seems to be the first requisite (R. 129–130). [Italics added.]

The testimony admits that the machines alone are incapable of diagnosing disease.

The trial court found (1) that the leaflets entitled "The Road to Health" accompanied the devices while in interstate commerce (R. 164); (2) that the leaflets claimed diagnostic values and therapeutic effects for the machines in many conditions (R. 165, Finding 4) and that they represented that the machine will register the exact nature of any disease (R. 165, Finding 5); (3) that the master model was incapable of diagnosing disease by registering pathological changes in the body (R. 165–166, Finding 5); and (4) that the principles on which the machines were claimed to operate were impossible of practical application with these instruments (R. 166, Finding 7).

The falsity of the claims of diagnostic capabilities for the small models was treated under the general finding last mentioned. The court also found that the claims of therapeutic and curative effect were false and misleading (R. 166). The court concluded that the devices had been shipped in interstate commerce and were misbranded, and that petitioner was entitled to a decree of condemnation (R. 167), which was entered on January 27, 1947 (R. 168-169).

Upon appeal to the Circuit Court of Appeals for the Fifth Circuit, by Urbeteit alone, the judgment was reversed and the cause remanded for further proceedings (R. 179–183) on the grounds that the leaflets had not accompanied the devices while in interstate commerce and, hence, did not constitute labeling within the meaning of the Act,[1] and that the trial court had erred in refusing to hear certain testimony.[2]

---

[1] Although it did not expressly so hold, the court indicated doubt that the leaflets could properly be considered as in the nature of labeling for the machines because it thought the leaflets to be advertising (R. 181–182).

[2] The trial court excluded the testimony as to diagnoses made by the respondent because it thought that the diagnoses were based upon the machine examination (R. 131, 159, 161, 163). The Circuit Court of Appeals interpreted the record as showing that respondent used all known methods of diagnosis (R. 182). The trial court excluded testimony of respondent's patients as to the benefits they had received through use of the device because it thought it was offered (1) as opinion evidence on medical questions and was thus incompetent, or (2) as hearsay evidence as to what some physician not in attendance at the trial had told the patients

SPECIFICATION OF ERRORS TO BE URGED

The Circuit Court of Appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the leaflets "The Road to Health" did not "accompany" the devices, within the meaning of Section 201 (m) of the Act.

3. In failing to affirm the judgment of the district court because of false and misleading claims of diagnostic capabilities despite alleged errors in exclusion of evidence offered to show the claimed therapeutic values of the machines.[3]

REASONS FOR GRANTING THE WRIT

1. (a) Section 201 (m) provides that—

> (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

This case presents for the first time in this Court the question of the proper interpretation of the

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as to their diseases (R. 160–163). The Circuit Court of Appeals held that the witnesses should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183).

[3] Error is not assigned as to the rulings below with respect to the exclusion of evidence by the trial court. For reasons hereinafter set forth (pp. 18-21), petitioner submits that even if the court below did not err in holding the excluded evidence admissible, petitioner is entitled to a judgment of condemnation because of admittedly false representations on an issue to which the excluded evidence did not pertain.

phrase "accompanying such article". The opinion of the Circuit Court of Appeals holds that the leaflets in question did not "accompany" the machines because they were not shipped substantially simultaneously. As we read the opinion below, it decides that the labeling and the device or article must go along with each other in a physical sense; that the two must be shipped or received at or about the same time; that such a construction is required because "in a criminal and forfeiture statute the meaning cannot be stretched" (R. 180–181).

This holding is in direct conflict with the decision of the Circuit Court of Appeals for the Seventh Circuit in *United States* v. *Kordel*, decided November 6, 1947, not yet reported.[4] That opinion is set forth in the Appendix, *infra*. The test there applied was not "physical contiguity" in shipment or receipt,[5] but the relationship of the literature to the product. Was the literature to be utilized with the product to inform the purchasing public of its uses and purposes? See also *United States* v. *7 Jugs, etc., of*

[4] We are advised that a petition for certiorari will be filed in the *Kordel* case.

[5] In the *Kordel* case, it was pointed out in the opinion that "In some cases [the literature] was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively."

Dr. Salsbury's Rakos, 53 F. Supp. 746 (D. Minn.).[*] It is the Government's position that it is not necessary that descriptive literature be shipped in the same container with, or at the same time as, the article to which it relates in order for the literature to constitute labeling "accompanying" an article within the meaning of the Act. Rather, the relevant factors are interdependence of the literature and the article, their common origin, destination, display and distribution, and their purpose and use together.

(b) The interpretation of the phrase "accompanying such article" is of vital importance in the enforcement of the Federal Food, Drug, and Cosmetic Act. Since the enactment of the law, it has become a common practice to ship articles separately from leaflets, circulars, and booklets containing false and fantastic claims of diagnostic capabilities and therapeutic values, in studious attempts to evade the Act. As soon as one plan to escape the statutory ban is met, another is concocted by the purveyors of false nostrums and panaceas. If such evasive schemes can be successfully perpetrated, the salutary purpose of the Act will be defeated. The decision of the Circuit Court of Appeals will, at least in the Fifth Circuit, prevent the statute from being invoked

[*] *Alberty* v. *United States*, 159 F. 2d 278 (C. C. A. 9), upon which the court below largely relied, was, as the opinion in that case discloses, complicated by deficiencies in the information which was attacked.

against fraudulent and dangerous drugs and devices so long as their distributors utilize the simple scheme of seeing to it that the article is shipped apart from the labeling. Considering the remedial purposes of the Act, and the reasons for its enactment (*United States* v. *Dotterweich*, 320 U. S. 277, 280; *United States* v. *Sullivan*, No. 121, decided January 19, 1948), it is clear that Congress did not intend to permit any such evasion of the statutory requirements.

2. These leaflets were by nature "labeling" notwithstanding they also constituted advertising. The leaflets in the instant case were prepared by the respondent, and were supplied by him to the consignee for the purpose of explaining to prospective purchasers, renters, and patients the usefulness of the device and how it is employed in the diagnosis, cure, mitigation, and treatment of various diseases. Without the leaflets the devices lacked labeling in that nowhere else was this essential information supplied. The label of the devices bore only "U. S. Patent Sinuothermic Trade Mark" (R. 20). Obviously such a label does not explain the purposes for which the device was intended to be used, but the leaflet did contain that information in elaborate detail. Thus, the leaflets were intended to and did serve the purposes of labeling equally as much as if they had been physically attached to the machines. Without the extravagant claims made in the leaflets it

is doubtful that the devices could be rented or sold or that the services of the machines could have been sold to patients.

It was the purpose of Congress in enacting the Federal Food, Drug, and Cosmetic Act in 1938 to include promotional material of this kind within the definition of labeling. The Food and Drugs Act of 1906, as amended [21 U. S. C. 10 (1934 ed.)], provided that a drug was to be deemed misbranded "If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent." The word "contain" was specifically inserted by amendment in 1912 to cover circulars or printed matter placed inside the package. *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510. Nothwithstanding the 1912 Amendment, unscrupulous purveyors of nostrums were able readily to circumvent the law by adopting the practice of shipping, separate from the drug to which it related and which it described, literature containing false and fraudulent claims.

Thus, prior to 1938, the law protected the public only where false claims were made on the label or package or on circulars within the package. The terms of the old law were well designed to accomplish that purpose, and Congress in the new law could have employed the same language if it had

intended no greater coverage.[7] It was apparent, however, that there was need for extending the consumer protection to items of labeling which occurred outside the package. The law was changed therefore to include any "written, printed or graphic matter upon * * * or *accompanying* any article."

Walter G. Campbell, then Chief of the Food and Drug Administration, explained the purpose of the definition at the Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, Seventy-Third Congress, Second Session, on S. 1944, p. 16:

> At the present time the law has control over those statements that are attached to or that accompany the package in the form of circulars. For the purposes of the subsequent requirements of this bill these have been divided into two classes; first, "label" meaning the principal label or labels upon the immediate container of any food, drug, or cosmetic, and upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic. Then the term "labeling" is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug,[8] or cosmetics.

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[7] Cf. *United States* v. *Walsh*, 331 U. S. 432.

[8] Devices were included within the definition of drug in this bill (Section 2 (b)).

The fact that the leaflet "The Road to Health" has some of the characteristics of advertising does not exclude it from the definition of labeling under the Act. *United States* v. *Research Laboratories,* 126 F. 2d 42 (C. C. A. 9), certiorari denied, 317 U. S. 656; *United States* v. *Lee,* 131 F. 2d 464 (C. C. A. 7). An item of literature of this kind may at once serve the dual purpose of advertising and labeling. In the *Research Laboratories* case, the court said (p. 45):

> Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. This assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

3 (a). The evidence which the Circuit Court of Appeals held the District Court to have improperly excluded did not relate to the false representations as to the diagnostic capacity of the machines but to the alleged misrepresentations as to curative value. The misrepresentations as to diagnostic capacity were established by respondent's own admission, *inter alia.* Thus, any error in the exclusion of evidence which did not

disprove the making of such misrepresentations would not defeat the Government's right to condemnation.

The Statement sets forth some of the claims of diagnostic capabilities made for the devices by the leaflets (*supra*, pp. 7–8). The trial court found that these claims represented that the devices would register the exact nature of any disease and would diagnose diseases (R. 165, Findings 4–5). Urbuteit's testimony was that the machines—even the ones that had meters—would not register what the patient's ailment was (R. 129–130). He said that the device "merely locates where there is something wrong." The Government's evidence was overwhelming that the machines could not do even that. The Circuit Court of Appeals pointed out that the respondent's testimony "only claimed the machine to be an aid in diagnosing." His testimony was that the machine "only located the spot where the abnormal tissue was" after which "it was then a matter of judgment as to what the disease was" (R. 182).

The labeling claims are irreconcilable with this testimony. They assert that the machine "leaves out all guess work"; that it "registers exactly and never makes a mistake"; and that it removes the necessity of having "someone guess at what your ailment is." See pp. 7–8, *supra*. Respondent's testimony implicitly admitted that

those claims are falsehoods. The Government's evidence gave them the lie explicitly.

Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are false and misleading in all respects. Petitioner is entitled to a decree of condemnation if it shows that any one of the various claims made in the labeling is either false or misleading in any particular. Section 502 (a); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C. C. A. 6); *United States* v. *Six Dozen Bottles, etc.*, 158 F. 2d 667, 669–670 (C. C. A. 7); and *United States* v. *One Device * * * Colonic Irrigator*, 160 F. 2d 194, 200 (C. C. A. 10).

The evidence that was excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158–163). The Circuit Court of Appeals concluded that the evidence from respondent as to his diagnoses was erroneously excluded because the diagnoses had not been made solely by the machine.[9] It concluded also that the testimony of the lay witnesses was erroneously excluded because they should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183). The admission of the evidence

[9] The record makes it clear that this testimony was offered to show the diseases which respondent's patients would testify were cured by use of the machine. See R. 158, 160–161, 162–163.

within those limits would have had no bearing upon the diagnostic capabilities of the machines.

Since it appears from the undisputed testimony and from the admissions of the respondent that the machines are incapable of diagnosing disease, and since the machines were represented as having diagnostic capabilities, petitioner is entitled to a decree of condemnation if it prevails on the "accompaniment" issue, irrespective of whether the court below was correct in holding other evidence relating to the curative value of the machines improperly excluded.

(b) Furthermore, the decision below on the accompaniment issue necessarily calls for a dismissal of the libel. If the court below was wrong on that point but correct in reversing the judgment because of the exclusion of evidence, respondent would at most be entitled to a new trial at which the excluded evidence could be admitted.

CONCLUSION

The primary question here presented is one of importance in the administration of the Federal Food, Drug, and Cosmetic Act. The decision below enables unscrupulous distributors of medical devices to introduce their wares into interstate commerce unhampered by the Act through the simple expedient of separating the product and the false representations during interstate transportation. The decision below, if permitted to

stand, will impair the health and lives of many persons who will rely upon this type of fraudulent device instead of obtaining competent diagnoses of serious diseases. There is a conflict in the decisions of the Circuit Courts of Appeals. We respectfully submit that this petition for a writ of certiorari should be granted.

PHILIP B. PERLMAN,
Solicitor General.

FEBRUARY 1948.

APPENDIX

In the United States Circuit Court of Appeals for the Seventh Circuit

No. 9151—October Term and Session, 1947

THE UNITED STATES OF AMERICA, PLAINTIFF-APPELLEE

vs.

LELORD KORDEL, DEFENDANT-APPELLANT

Appeal from the District Court of the United States for the Northern District of Illinois, Eastern Division

November 6, 1947

Before EVANS and SPARKS, *Circuit Judges,* and LINDLEY, *District Judge*

SPARKS, *Circuit Judge.* Appellant was charged by three criminal informations with violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. sections 301, *et seq.* He waived jury trial and, upon trial by the court, was found guilty and fined $200 on each of the twenty counts contained in the three informations. The appeal is from those judgments.

The facts as to the shipping of the drugs and the literature alleged to constitute the misbranding charged in the informations were entirely stipulated. Error is asserted in the court's find-

ing that that literature "accompanied" the drugs in interstate commerce in the purview of the Act prohibiting the introduction or delivery for introduction of any drug that is misbranded. Other contested issues relate to the degree of proof necessary in a criminal proceeding under the Act, whether the Act should be strictly construed, and whether prosecution should have been by indictment rather than by information.

Appellant is a self-styled authority on nutrition and vitamins. He testified that he had written many papers on the subject of vitamins, herbs, minerals, and nutritional diet subjects in general, securing the material for preparation of his papers from books. Operating under various trade names, he had been producing and marketing his own products since January 1941, largely through "health food" stores. The products appear to be, for the most part, compounded of various vitamins, minerals, and herbs. No charge of falsehood is made as to the principal labels printed on the packages in which each is contained. These labels give the name of the article and distributor, content, recommended dosage; and, in some cases, the alleged daily minimum requirement of the vitamins or minerals therein. Otherwise they give no indication as to their intended uses.[1] The misbranding charged is contained in a number of printed pamphlets and circulars, and one display placard. The modes of distribution of this literature differed as charged

[1] The articles involved in the three informations are named "Gotu Kola," "Minerals plus Chlorophyll and Vitamin D," "Cetabs," "Fenugreek Tea," "Fero-B-Plex," "Bolax," "Ormotabs," "Ribotabs," "Kordel Tablets," "Everm," "Kordel A," "Garlic Plus," "Niamin," and "Sarsaparilla Tea."

in the various counts of the informations. In some cases it was contained in the carton in which the articles were shipped. More often, it was separately shipped to the same consignees, and, in at least one case, a period of a year and a half intervened between the shipment of the product and the literature, respectively.

Section 301 of the Food and Drugs Act as amended in 1938, 21 U. S. C. A. sec. 331, prohibits the introduction or delivery for introduction into interstate commerce of any drug that is misbranded; section 502, 21 U. S. C. A. sec. 352, provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201 (m), 21 U. S. C. A. sec. 321 (m), defines the term "labeling" to include all labels and other written, printed, or graphic matter "(1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container (*United States* v. *Research Laboratories,* 126 F. 2d 42), nor even that it be shipped simultaneously (*United States* v. *Lee,* 131 F. 2d 464; *United States* v. *7 Jugs * * * Rakos,* 53 Fed. Supp. 746; *United States* v. *Paddock,* 67 Fed. Supp. 819).

Appellant contends that the cases referred to are not applicable for the reason that all involved civil proceedings rather than criminal, and further, that the literature here involved was not only not shipped in the same carton with the

products in all cases, but neither was it intended by him that product and literature should be placed together by the dealer to whom they were sent. His theory apparently is that the matter was not intended for labeling, but for advertising. He points to the fact that all of the printed matter was intended either to be mailed out or to be sold, as indicated by the fact that with the exception of the one display placard, each piece either contained a price mark or a mailing permit with space for address. This, he contends, supports his theory that product and literature were not to be distributed together, hence cannot be said to accompany each other.

We find two answers to this contention. In the first place, labeling and advertising are not mutually exclusive, and the same matter may serve both purposes. As the Court of Appeals for the Ninth Circuit states in *United States* v. *Research Laboratories,* 126 F. 2d 42, "Most, if not all, labeling is advertising. The term 'labeling' is defined in the Act as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising." See also *United States* v. *Paddock,* 67 Fed. Supp. 819. In the second place, the placing of the mailing permit or the price tag on the literature cannot insulate appellant from liability for introducing the drugs and their related descriptive matter into interstate commerce together by consignment to the same consignee for distribution by him. The evidence is clear that the booklets were actually displayed on racks close to the counter where the products were sold and that they were necessary

to inform the purchasing public of the uses to which these products were to be put.

We agree with appellee that "the correct concept of 'accompaniment' is one of a commercial or business association." As stated in the *Rakos* case, *supra,* "misbranding has true significance only in terms of the consumer. * * * 'Accompany' as used in this Act is used to describe a relationship between an article of drug and its labeling. Since there 'can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates' (citing the decision of this court in *United States* v. *Lee, supra*) the booklets here involved should be scrutinized from this viewpoint. In the sense just stated, if the booklets are not labeling, then the products * * * have none."

We, too, are convinced that the test is not of physical contiguity but of textual relationship. Viewed thus, the products and literature here involved were interdependent because without the latter, the former lacked the labeling necssary to inform the purchasing public of their uses and purposes—it is significant that the labels printed on the immediate containers did not indicate the purposes for which the articles were to be used. Hence, the literature was intended and essential to explain the alleged uses of the products. They constituted a supplement to the label physically attached to the product container. One of the health-food dealers in whose store the Kordel products were sold admitted that if he were buying one of the products he would have to go to "reliable sources" to know to what use to put

the product. Presumably those reliable sources were the booklets displayed in racks close by the counter where the drugs were dispensed or lying on the counters where they were available to the public and could be picked up and examined. Some also were wrapped with merchandise or handed to customers.

We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be distributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. To hold otherwise would be to permit evasion of the Act by the very easy subterfuge of printing a purchase price or a mailing permit on advertising matter otherwise unquestionably accompanying products into interstate commerce.

With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, "Nutrition Guide," and "What you can do about relieving the agonies of Arthritis," were written by appellant who, in the latter, is described as "America's leading vitamin and diet expert." "Health Today, Spring 1945," is edited by the same "famous nutrition and vitamin authority." While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a

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vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair, and eyes; normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver, and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous break-down, sterility, and paralysis.

Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while

delay in correct diagnosis and treatment for those conditions might render the treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. Hé branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were harmful, replied, "They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy."

All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act.

Appellant contends that, since the current proceedings are criminal, he is entitled to a strict construction of the Act, with proof of the violation, if any, beyond a reasonable doubt. Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in Sutherland on Statutory Construction (Vol. III, sec. 7202), "The public and social purposes served by such legislation greatly exceed

the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties." To the same effect is the ruling in *United States* v. *Dotterweich,* 321 U. S. 277, where the Court said, "The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."

We think there can be no doubt of the sufficiency of the evidence to sustain the charge beyond a reasonable doubt.

Appellant strongly relies upon *Alberty* v. *United States,* 159 F. 2d 278, to sustain his proposition that booklets and the like, not shipped at the time of the articles, do not "accompany" the article when they are introduced or offered for introduction into interstate commerce, and consequently cannot "then and there" misbrand them. The Circuit Court of Appeals for the Ninth Circuit there reversed an order overruling a demurrer to an information and remanded the cause with directions to dismiss the information. It distinguished three of the cases to which we have referred (*United States* v. *Research Laboratories, United States* v. *7 Jugs * * * Rakos,* and *United States* v. *Lee*), on the ground that all involved civil proceedings and construed the Act liberally. We have already indicated that under

the authorities cited, we do not consider the distinction applicable to the construction of the statute here involved. To the extent that the court limits the definition of the word "accompany" to mean only physical association and contiguity, we do not agree with its reasoning and are convinced that it is not in harmony with those authorities.

We find no merit in appellant's contention that he should have been prosecuted by indictment rather than by information. Section 303 (a) upon which the informations were based (21 U. S. C. A. sec. 333 (a)) provides that any person violating any of the provisions of section 201 shall be guilty of a misdemeanor, and subject to imprisonment for not more than one year or a fine of $1,000 or both, unless he has already been convicted of a prior offense under the same section. The charges were brought under this section. That being the case, there was no necessity for prosecution by indictment. See *United States* v. *Wells Co.*, 186 Fed. 248 (holding violation of the 1906 Food and Drugs Act not an infamous crime). See also *Falconi* v. *United States*, 280 Fed. 766, and cases there cited.

Judgments affirmed.

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Clerk of the United States Circuit Court of Appeals for the Seventh Circuit.

U. S. GOVERNMENT PRINTING OFFICE: 1948

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In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 13

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES

OPINION BELOW

The opinion of the Court of Appeals (R. 179–183) is reported at 164 F. 2d 245.

JURISDICTION

The judgment of the Court of Appeals was entered on November 7, 1947 (R. 183). The petition for a writ of certiorari was filed on February 6, 1948, and was granted on April 19, 1948 (R. 185). The jurisdiction of this Court was invoked under Section 240 (a) of the Judicial Code, now 28 U. S. C. 1254.

QUESTIONS PRESENTED

Certain devices, and leaflets claiming that the devices were useful in the diagnosis and therapy of numerous ailments, were shipped in interstate commerce by respondent to the same consignee, but separately and at different times. The leaflets were sent for the purpose of describing the capabilities of the device to prospective purchasers and users; the leaflets and device were displayed together, and the device itself bore no labeling other than name and serial number.

The principal question presented is whether, as a matter of construction of the pertinent interrelated provisions of the Federal Food, Drug, and Cosmetic Act, the device is subject to condemnation. Section 304 (a) provides for the condemnation of any device that is "misbranded when introduced into or while in interstate commerce"; Section 502 (a) defines a device as "misbranded" if its "labeling" is false or misleading in any particular; and Section 201 (m) defines "labeling" to include "written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article".

Subsidiary questions are whether the evidence supports the district court's finding that the "labeling" of the device was false and misleading in respect of the representations regarding its diagnostic capabilities; and, if so, whether the

Government is therefore entitled to a decree of condemnation, even assuming that the district court improperly excluded certain evidence offered by respondent to substantiate the representations regarding the therapeutic value of the device.

STATUTORY PROVISIONS INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, *et seq.*), are set forth in the Appendix, pp. 43–44.

STATEMENT

The Pleadings. On January 9, 1947, a second amended libel of information was filed in the United States District Court for the Northern District of Florida, under Section 304 of the Federal Food, Drug, and Cosmetic Act, seeking the seizure and condemnation of 16 "articles of device" labeled "Sinuothermic" (R. 11–15). The libel alleged that the device was "misbranded" within the meaning of Section 502 (a) of the Act because its "labeling" was false and misleading. In particular, the libel alleged that the device was "accompanied" in interstate commerce by a leaflet entitled "The Road to Health", containing false and misleading representations regarding the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment, and prevention of disease (R. 13).

Fred Urbeteit, the respondent, who is a naturopathic physician (R. 119), appeared as claimant of ten of the devices of the so-called treating unit type (R. 5, 12, 10), and J. J. H. Kelsch, an unlicensed naturopathic and chiropractic physician (R. 32), appeared as claimant of the remainder of the devices, two of which were the so-called master units and four of which were of the treating unit type (R. 5, 12, 10). Together they filed a "consent to amendment and claim" which admitted factual recitals in previous pleadings, renewed the statements of ownership, and admitted that the sixteen devices and a number of leaflets, entitled "The Road to Health", were introduced into interstate commerce at Tampa, Florida, for shipment to Cincinnati, Ohio, and were in possession of Kelsch at Cincinnati when the libel was filed. They denied that the devices and leaflets were shipped together or that they related to each other, and neither admitted nor denied the dates of the shipments because of lack of exact knowledge. They also denied that the leaflets accompanied the devices in interstate commerce and that the representations made in the leaflets were false or misleading. (R. 10–11, 11–15.)

The Evidence. The case was tried by the court without a jury (R. 15). The evidence showed that Urbeteit was the shipper (R. 24, 29–31). Four shipments of the devices were made by means of the Railway Express Agency, the first

on July 23, 1945, the second on August 14, 1945, the third on August 18, 1945, and the fourth on September 21, 1945 (R. 24–25).

Kelsch testified that he had received a three weeks' course of instruction from Urbeteit in Florida in June 1945, and had received a diploma in absentia (R. 25–26). While there, arrangements were made for the purchase of some devices and for the rental of others, contingent upon Kelsch's ability to make financial arrangements in Cincinnati (R. 29). As a part of the same transaction, Urbeteit agreed to supply a quantity of the leaflets, "The Road to Health", for the purpose of explaining the machines to Kelsch's patients (R. 29). Accordingly, the leaflets were shipped to Kelsch in bulk supply and received by him. Pursuant to an understanding between Kelsch and Urbeteit, some of the leaflets were mailed out to patients and others were shown to patients during consultation. (R. 29–30.)

Kelsch first testified that he received the leaflets, by parcel post, after the machines were shipped to him (R. 29, 6), but later stated that he did not know the exact date the leaflets were received. He stated that they were received sometime around September (R. 31). Some of the leaflets were found on September 5, 1945, in and on a desk in Kelsch's main consulting room within the reach and view of patients who consulted him there. The devices were in the ad-

joining consulting rooms and treating rooms. The devices bore a label which contained the statement "U. S. Patent Sinuothermic Trade Mark" together with a serial number (R. 20). No labeling other than the leaflets, "The Road to Health", was sent to Kelsch. Some machines were sold or rented to patients by Kelsch (R. 22–23, 30).

In addition to many representations of therapeutic value involving, among many others (see R. 165), such variegated diseases as cancer, tuberculosis, diabetes, appendicitis, heart disease, hay fever, infantile paralysis, menstrual discomfort, peritonitis, nervousness, and prostate trouble, the leaflet, "The Road to Health",[1] in part describes the diagnostic capabilities of the machines as follows:

IMPORTANCE OF EXAMINATION

> You must realize the all importance of being examined the Sinuothermic way, which leaves out all guess work as Sinuothermic locates the cause and registers exactly [p. 1, col. 3].
>
> * * * * *
>
> CANCER DANGER SIGNAL
>
> * * * At the Sinuothermic Institute no one is ever treated without first being thoroughly examined, and it should be remembered that NO really COMPETENT doctor

[1] This exhibit (R. 13, 19) is on file with the Clerk of this Court. Reproductions of this exhibit have also been filed with the Clerk.

will treat a condition that might be a cancer without first making a careful examination. INSIST on a thorough examination no matter who your doctor is. Be examined with Sinuothermic which registers exactly and never makes a mistake [p. 1, col. 4].

* * * * *

BE EXAMINED

Why have someone guess at what your ailment is when at the Sinuothermic Institute, Inc., you can be examined with that never failing Sinuothermic machine which leaves out all guess work and registers exactly [p. 1, col. 4].

SINUOTHERMIC EXAMINATION

Dr. Urbeteit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but she was also pregnant about 5 months. * * * [p. 2, col. 6]

* * * * *

SCIENCE AT ITS PEAK

Sinuothermic is the last word in scientific discoveries. Sinuothermic is a tester of human tissue. You could liken Sinuothermic to the tester they use to test your radio tubes with * * * Sinuothermic registers exactly the condition of human tissue [p. 2, col. 6].

The general representation that the machine "locates the cause of any ailment and registers exactly" appears frequently throughout the leaflet.

The Government's evidence showed that the Sinuothermic machine consists of a number of electrical units mounted in a wooden cabinet (R. 39). The machine is designed to draw electricity from an ordinary household wall socket, to control the full line voltage (electrical pressure) by turning in variable amounts from zero to the full line voltage (115–120 volts), to step this voltage down to a maximum value of 60 volts, and to deliver current to the patient so that it will flow through the body between two pad electrodes that are applied to the bare skin (R. 39–44, 50–52, 164). The small machines differed from the master units only in the omission of the four indicating meters (R. 43, 164).

The Government's evidence showed, further, that even the master model, which had four indicating meters, was incapable of registering any pathological changes in the body. This was because the meters were primarily affected by the patient's body resistance to electrical current and because internally the current is conducted through body fluids and not body tissues (R. 43, 51–52). The so-called treating units did not have the four indicating meters (R. 43). The expert testimony for the Government was that these machines were without value in the diagnosis of

the disease conditions involved (R. 72, 76, 79–80, 83–85, 88–89, 91, 93, 96–97, 99–100, 104–105, 109–112).

Urbeteit described his method of "diagnosis" as follows: he said that when the current from the machine encounters a lesion in the human body, the meters will register "the amount of intensity or resistance there is in that particular area" (R. 126–127, 128–130). He admitted, however, that the machines alone are incapable of diagnosing any specific disease:

> The meters do not tell me what the ailment is, it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of obstruction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is * * * [R. 129].
>
> * * * * * * * *
>
> There is no way of registering the kind of ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever that something is wrong it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. But I find in all my experience it is not necessary to go to all that trouble to take those tests. As long as the patient gets well, that seems to be the first requisite [R. 129–130].

The expert testimony for the Government contradicted this claim that the machine could "locate where there is something wrong" (R. 76, 79–80, 93, 96–97, 99–100, 104–105, 109–112).

The respondent offered to present testimony by various patients as to the benefits they had received through use of the device. The trial court excluded this testimony on the ground that it was offered (1) as opinion evidence on medical questions and was thus incompetent, or (2) as hearsay evidence as to what some physician not in attendance at the trial had told the patients as to their diseases. (R. 160–163.) The court also excluded testimony by respondent as to "diagnoses" made by him through use of the machine (R. 131, 159–161, 163).

The Findings. The trial court found (1) that the leaflets entitled "The Road to Health" accompanied the devices while in interstate commerce (R. 164); (2) that the leaflets claimed diagnostic values and therapeutic effects for the machines in many conditions (R. 165, Finding 4) and that they represented that the machine will register the exact nature of any disease (R. 165, Finding 5); (3) that the master model was incapable of diagnosing disease by registering pathological changes in the body (R. 165–166, Finding 5); and (4) that the principles on which the machines were claimed to operate were impossible of practical application with these instruments (R. 166, Finding 7). (The falsity of the claims of diag-

nostic capabilities for the small models was treated under the latter general finding). The court also found that the claims of therapeutic and curative effect were false and misleading (R. 166).

The Rulings Below. The district court, concluding that the devices were shipped in interstate commerce and misbranded in violation of the Act, held that the Government was entitled to a decree of condemnation (R. 167), which was entered on January 27, 1947 (R. 168–169). Upon appeal to the Court of Appeals for the Fifth Circuit, by Urbeteit alone, the judgment was reversed and the cause remanded for further proceedings (R. 179–183) on the grounds (1) that the leaflets had not "accompanied" the devices while in interstate commerce and hence did not constitute labeling within the meaning of the Act,[2] and (2) that the trial court had erred in excluding the testimony offered by respondent. The Court of Appeals held that the respondent's patients should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183); and that Urbeteit, as "a licensed doctor of some twenty years practice," should have been permitted to "express expert opinions" on the efficacy of his machine (R. 182–183).

[2] Although it did not expressly so hold, the court indicated [redacted] that the leaflets could not properly be considered as labeling for the machines because they were more in the nature of advertising (R. 181–182). See pp. 32–37, *infra*.

SUMMARY OF ARGUMENT

I

A. The history of federal food and drug legislation is essentially empiric: it is a chronicle of the successive efforts by Congress to plug one loophole after another through which the unscrupulous have been able to frustrate the purposes of the legislation. In 1938, after a series of ineffectual amendments to the old 1906 law, Congress enacted a broad and comprehensive measure, the Federal Food, Drug, and Cosmetic Act, which, it was hoped, would at last "meet the requirements of consumer protection under modern conditions" (see *infra*, p. 19).

The principal question presented in this case and in *Kordel* v. *United States* (No. 30) is, essentially, whether Section 201 (m) of the 1938 Act contains an easy loophole which reduces it to an empty formulation of words having no practical significance. In particular, the issue is whether the court below is right in holding that the words "accompanying such article," as used in Section 201 (m), require that article and leaflet must travel together in interstate commerce over the same route and at the same time. The court below rejected the Government's contention that the concept of "accompaniment" is a practical one, governed by considerations based on economic realities and common-sense. We be-

lieve with this Court (see *United States* v. *Dotterweich*, 320 U. S. 277, 280) that regard for its humanitarian purposes "should infuse construction of the legislation".

The Government submits that a leaflet which (a) explains the uses to be made of a device, (b) is sent in interstate commerce by the same shipper to the same consignee, and (c) is displayed with and is intended to be distributed with the device, "accompanies" the device for all practical purposes, and therefore should also be regarded as "labeling" for purposes of the statute, even though the leaflet is shipped separately and at a different time from the device. Otherwise, if the court below is right, the unscrupulous have a ready-made means for evasion of the salutary purposes of the Act.

B. Printed matter can constitute both advertising and labeling; it does not necessarily lose its character as labeling because it has some characteristics of advertising.

II

The leaflets contained representations as to both the diagnostic and therapeutic capabilities of the machine. The evidence excluded by the trial court related only to the alleged therapeutic value of the machine. The evidence overwhelmingly established the falsity of the claims regarding diagnostic capabilities. Since a decree of condemnation can properly issue if it is shown that

any one of the various claims in the labeling is false, the Government is entitled to a decree of condemnation, even if it be assumed that error was committed in excluding evidence as to the therapeutic powers of the machine.

ARGUMENT

Preliminary Analysis. In order to prevail in this case, the Government had to prove the following: (1) That respondent's machines constituted a "device"; (2) that the device was "accompanied" by leaflets which constituted "labeling"; (3) that these leaflets were false or misleading, and hence that the device was "misbranded"; and (4) that the device was misbranded "when introduced into or while in interstate commerce."

No contention is made that the Sinuothermic machine is not a "device". Nor is there, in our view, any serious question as to the false and misleading character of the leaflets, "The Road to Health". The principal question is whether the court below erred in ruling, as a matter of law, that the leaflets did not "accompany" the device, and that consequently the latter was not "misbranded when introduced into or while in interstate commerce." This ruling required dismissal of the libel; but the court below went on to hold that the trial court had erred in excluding certain evidence offered by respondent and that the "case ought to have been more fully

tried" (R. 183). This latter ruling would, in itself, require only a remand for a new trial. The judgment formally entered by the court below was that the decree of the district court should be reversed and the cause remanded for further proceedings consistent with its opinion (R. 183).

In this posture of the case, the Government urges here that the decree entered by the district court was correct in all essential respects and should be reinstated without further proceedings. In our view the district court's construction of the Act was proper and a decree of condemnation should issue, even assuming that error was committed in excluding respondent's offer of proof, because such proof related only to the alleged therapeutic value of the device; the findings as to the false and misleading character of the representations regarding the diagnostic powers of the machine are amply supported by the evidence, and in themselves form a sufficient basis for the decree.

I

RESPONDENT'S DEVICE WAS "ACCOMPANIED" BY FALSE AND MISLEADING LEAFLETS, AND HENCE WAS "MISBRANDED WHILE IN INTERSTATE COMMERCE."

The essential difference between the construction made by the court below and that urged by the Government relates to the word "accompanying" in Section 201 (m), which provides:

For the purposes of this Act—

* * *

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The court below held that, because the leaflets and devices did not travel together or at the same time during the interstate journey, the leaflets "did not accompany any of the devices while they were in interstate commerce * * *. Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched." (R. 181).

This in effect lays down the rule that there must be physical association of the printed matter and article during the movement in the channels of interstate commerce. We think that such a construction of the word "accompanying" is unduly narrow; and that, correctly construed, a leaflet which for all practical purposes is incident to and an integral part of the distribution of an article "accompanies" that article, even though it has no physical connection with the article during its interstate journey.

There can be no doubt as to the underlying purpose of the Federal Food, Drug, and Cosmetic Act. It was carefully devised to protect the ultimate consumer from misbranded and adulterated food, drugs, devices and cosmetics from the time they enter the channels of commerce until they

are purchased for consumption or ultimate use. *United States* v. *Sullivan*, 332 U. S. 689. In *United States* v. *Dotterweich*, 320 U. S. 277, 280, this Court said:

> The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

Nothing in the purposes or history of the Act indicates that Congress intended that its beneficial protective provisions could be evaded by the simple expedient of separate shipment of an article and the printed explanatory matter which, in a practical business sense, "accompanies" it.

The Food and Drugs Act of 1906 (Section 8) originally applied the term "misbranded" to "the package or label of [a drug or article of food] which shall *bear* any statement, design, or device regarding such article * * * which shall be false or misleading in any particular * * *" (Italics supplied) (34 Stat. 768, 770). This language was held inapplicable to false or misleading circulars enclosed in the package with the article. *United States* v. *American Druggists' Syndicate*, 186 Fed. 387, 391 (E. D. N. Y.).

The Act was promptly amended [37 Stat. 416; 21 U. S. C. 10 (1934 Ed.)] to provide that a

drug[3] was to be deemed misbranded "If its package or label shall *bear or contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent." (Italics supplied). The word "contain" was inserted by the 1912 amendment to cover circulars or printed matter placed within the package. *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510.

Notwithstanding this amendment, unscrupulous purveyors of nostrums were able readily to circumvent the law by adopting the practice of shipping, separate from the drug to which it related and which it described, printed matter containing false and fraudulent claims. Thus, prior to 1938, the law protected the public only where false claims were made on the label or package or on circulars within the package. It was obvious, however, that there was need for extending consumer protection to printed or graphic matter associated with and distributed in relation to an article but which appeared outside its package.[4]

[3] The Food and Drugs Act of 1906 did not cover therapeutic devices. Under the present Act, drugs and devices are similarly treated wherever possible. Compare § 201 (g) (2) and (3) with § 201 (h), and see §§ 501 and 502.

[4] This need was recognized by the persons charged with enforcement as early as 1917, when the Food and Drugs Act of 1906 had been effective for only 10 years. The Annual Report of the Bureau of Chemistry for that year contained a review of 10 years of enforcement and recommendations

The 1938 revision was considered in Congress as early as 1933. Many bills were introduced and discussed during the 5-year period of legislative consideration. Congress, by its responsible committees, expressed its clear purpose that the new law "must not weaken the existing laws", but "must strengthen and extend that law's protection of the consumer." S. Rep. No. 152, 75th Cong., 1st Sess., p. 1. The purpose of the 1938 enactment was stated in H. Rep. 2139, 75th Cong., 3rd Sess., p. 1, as follows:

> While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in scope to meet the requirements of consumer protection under modern conditions.
>
> The measure contains substantially all of the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception, and it extends the scope of the law to include cosmetics, therapeutic devices, and certain drugs that now escape regulation.

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for closing loop-holes in the Act of 1906. The report stated in part: "* * * the law fails to take cognizance of fraudulent statements covering foods or drugs which are not in or upon the food or drug package." Amendatory legislation was suggested, but it was not until 1933 that such legislation was offered. In that year, a general revision of the Act was proposed. S. 1944, 78rd Cong., 1st Sess.

See *United States* v. *Dotterweich*, 320 U. S. 277, 280, 282.

Walter G. Campbell, then Chief of the Food and Drug Administration, explained the purpose of the definition of labeling at the Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, 73rd Congress, 2nd Sess., on S. 1944,[5] p. 16:

> At the present time the law has control over those statements that are attached to or that accompany the package in the form of circulars. For the purposes of the subsequent requirements of this bill these have been divided into two classes; first, "label" meaning the principal label or labels upon the immediate container of any food, drug, or cosmetic, and upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic. Then the term "labeling" is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug, or cosmetics.

Clearly, therefore, the 1938 Act made the concept of "labeling" more comprehensive than that which existed under the earlier law, so that it would include not only the label and material within the package, but also all written, printed,

[5] Devices were included within the definition of drug in this bill. [S. 1944, Sec. 2 (b)].

or graphic matter in any way accompanying the article to which it relates. To paraphrase what this Court said in *United States* v. *Walsh*, 331 U. S. 432, with respect to another provision of the Act, it is impossible to say that the framers of the 1938 Act added the new language of 21 U. S. C. 321 (m) for the useless purpose of achieving the same result as had been reached under the 1906 Act without such language.

The Government submits that the proper construction of "accompaniment" should be governed by economic realities, viewed in the light of the objectives of the Act. "Accompaniment" expresses a relationship between article and labeling which is to be ascertained on the basis of a practical, common-sense judgment. To hold, as the court below did, that identity of time in transit is an essential requisite of "accompaniment" is, we submit, justified by neither the terms nor purposes of the Act. Transportation factors are relevant, but not controlling, in determining whether article and labeling are so integrally related as to constitute "accompanying" elements of a single interstate transaction.

The construction made by the court below is in conflict not only with that made by the Court of Appeals for the Seventh Circuit in the companion case, *United States* v. *Kordel*, 164 F. 2d 913 (No. 30, this Term), but also with the rulings of other federal courts. See *United States* v. *Re-*

search Laboratories, 126 F. 2d 42 (C. C. A. 9), certiorari denied, 317 U. S. 656; *United States* v. *Lee,* 131 F. 2d 464 (C. C. A. 7); *United States* v. *One Dozen Bottles, etc., Boncquet Tablets,* 146 F. 2d 361 (C. C. A. 4); *United States* v. *One Device* * * * *Colonic Irrigator,* 160 F. 2d 194, 195–196, 200 (C. C. A. 10); *United States* v. *7 Jugs* * * * *Rakos,* 53 F. Supp. 746, 756 (D. Minn.); *United States* v. *Paddock,* 67 F. Supp, 819, 68 F. Supp. 407 (W. D. Mo.); but cf. *Alberty* v. *United States,* 159 F. 2d 278 (C. C. A. 9).*

In the *Kordel* case, the court said (No. 30, R. 462–464):

> It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container * * * nor even that it be shipped simultaneously * * *.
>
> * * * * *
>
> We agree with appellee that the "correct concept of 'accompaniment' is one of com-

* Although there are fifteen states with comparable provisions in statutes patterned after the Federal Act, there are no reported state decisions interpreting the phrase "accompanying such article." States having statutes drafted according to the outline of the Federal Food, Drug and Cosmetic Act are: California, Connecticut, Florida, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Jersey, New York, North Carolina, Oregon, Tennessee, Virginia and Washington. See for example Florida Stat. (1941), Secs. 500.01–500.32.

> mercial or business association". * * *
>
> We, too, are convinced that the test is not of physical contiguity but of textual relationship * * *
>
> We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be disfributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. * * *

The Government's construction of "accompaniment" was set forth with exceptional lucidity in *United States* v. *7 Jugs* * * * *Rakos,* 53 F. Supp. 746, 755 (D. Minn.):

> * * * it is simply a question of determining in a given case whether the relationship between the article and the printed matter is sufficiently proximate to fulfill the requirement of accompaniment.
>
> * * * * * *
>
> * * * the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers * * *. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. * * * It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on

the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. The instant that the product Rakos entered the channels of commerce enroute to the Hatcheries, it was to all intents and purposes as much travelling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container * * *

Were not the factors just stated to be given primary consideration, there would be a multiplication of refinements. * * * The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate

journey of the drugs does not in my opinion control.

Here, as in the *Rakos* case, the devices and leaflets were interlocking units of a distributional scheme, and the leaflets described the purposes and uses of the devices. The leaflets were intended to be used not only by Kelsch, the consignee, but also by patients he treated and to whom he sold devices. Pursuant to understandings between Kelsch and Urbeteit, some of the leaflets were mailed out to patients and others were shown to patients during consultation (R. 30). The devices bore no information as to their purposes and intended uses. Without the leaflets, the devices lacked labeling; nowhere else is the user advised of the purposes to which the machines were to be put. The machines and leaflets were designed to be used together in furtherance of the use and commercial distribution of the machines. In a practical business sense the booklets did accompany the device as a part of a single transaction and distributional scheme from the inception of the interstate movement of each of the machines.

If the court below is correct, it would be necessary in every case to show a physical connection in the interstate movement of articles and printed material. Movement on the same train, truck, or other vehicle would be required as a practical matter, for only then could it be shown

that the articles and leaflets accompanied each other in interstate commerce. False representations as to the capabilities of diagnostic and therapeutic devices would in large measure thus be removed from the protective coverage of the Act. Such devices frequently do not go to their consignees in consumer sized packages. Many of them are bulky—as are the Sinuothermic machines—and a common practice is to ship the labeling separately. Items of printed matter identical in content, designed for the purpose of explaining the uses of a drug or device and intended to serve the purposes of labeling, would or would not constitute labeling, depending upon the accident of physical association at the time of transportation.

There would be no doubt, even under the construction of the court below, that these leaflets would constitute labeling if they had physically traveled together with the machines in interstate commerce. All that respondent did was to break this physical attachment, and whether for convenience or to evade legal requirements, he made separate shipment of device and leaflets. All other ties, except physical association in transit, remain. Without the machines, the leaflets had no purpose; and without the leaflets the machines could not easily be put to commercial use.

We find it impossible to believe that Congress intended to attach such significance to a severance in

physical proximity during the interstate journey. If physical association be the test, the result would be that printed matter sent on one day would constitute labeling while the same printed matter if sent only one day before or after would not constitute labeling, depending on whether the article to which it relates was in transit at the same time. The shipper would need only assure himself that machine and labeling were not moving in commerce simultaneously. Under the construction of the court below, the leaflet would not be labeling even though article and printed matter were presented to the consumer at exactly the same time.

The Act is concerned with distribution of articles (*United States* v. *Dotterweich*, 320 U. S. 277, 283), and the appropriate inquiry is whether the ultimate purchaser will be misled (*United States* v. *Two Bags* * * * *Poppy Seeds*, 147 F. 2d 123, 127 (C. C. A. 6)). As was said in the *Rakos* case, 53 F. Supp. 746 at 754, "misbranding has true significance only in terms of the consumer." Section 201 (m) is indeed but a futile gesture if the essential inquiry in its application goes only to the time the device and leaflet were in commerce, without regard to the substance of the transaction and its effect upon the consumer.

The court below mistakenly thought that its construction of "accompany" was required by the literal meaning of the word. "Accompany", the

court said, "means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched" (R. 181). It is far from clear, however, that the word "accompany" necessarily means *physical* contiguity. It should be noted, first, that the word is not defined in the Act. Secondly, the Government's construction is included among common dictionary definitions. Webster, for example, defines "accompany" to mean "to cause to be attended by," "to go with or attend as a companion or associate", "to go along with", and "to occur in association with" (New International Dictionary, 2d ed. 1948). The Oxford English Dictionary definitions include "to supplement [a thing] by [another]", "to go in company with", and "to associate, consort, or keep company with" (Murray ed. 1888). The synonyms given by Funk and Wagnalls include "escort, follow, join, wait on" (New Standard Dictionary, 1947).

Congress is familiar with the usage of the word "accompany" in the sense which we suggest. Every committee report prepared for the purpose of explaining proposed legislation to members is marked: "REPORT To accompany S. —" or "REPORT To accompany H. R. —". There is in that usage nothing more than the textual relationship of the report to the bill. No idea of physical attachment is necessarily intended.

It will be argued that, even if the leaflets "ac-

companied" and hence "misbranded" the device, it does not follow that the device was misbranded "when introduced into or while in interstate commerce", as required by Section 304 (a). According to this contention, the device was misbranded, if at all, only after its shipment in interstate commerce had been completed.

The answer to this argument is to be found in the history of the applicable statutory provisions. Section 304 (a) of the present Act is derived from Section 10 of the old 1906 Act, 34 Stat. 768, 771, 21 U. S. C. A. 14. Under Section 10, seizure was available as to any "article of * * * drug * * * that is * * * misbranded * * * and is being transported from one State * * * to another * * *". As has been shown above, pp. 17–18, the concept of "misbranding" under Section 8 of the 1906 Act was narrowly restricted to printed matter in the package or on its label; accordingly, Section 10 was framed in terms of actual physical misbranding during the interstate journey of the article.

However, Congress has in the present Act expanded the concept of misbranding beyond this limited area of actual physical contiguity of article and labeling. An article is now "misbranded" under the Act if its labeling, whether it be printed matter on the article, or any of its wrappers or containers, or "accompanying" it, is false or misleading. To hold that, in circum-

stances such as are here present, the device is "misbranded" but not while "in interstate commerce", is to hold that Congress has expanded the words but not the substance of the 1906 Act. It would mean that the substantive amendments made by Congress to enlarge the scope of "labeling" are entirely nugatory because it failed to adjust similarly the jurisdictional provisions in Section 304 (a). This would for practical purposes require that "accompanying" be construed to mean physical attachment, and the purpose of Congress to close loopholes in the 1906 law will have been thwarted.

It is respectfully submitted that where, as here, the device is misbranded in the hands of the consignee because of false and misleading printed matter which was sent to him separately and at a different time, the printed matter "accompanied" the device and the latter was misbranded from the instant that it entered the channels of commerce. The interstate transaction must be viewed in its entirety as a single interrelated episode; and the Act is not to be eviscerated by reading the jurisdictional provisions of Section 304 (a) into the definition of labeling so as to deprive the phrase "accompanying such article" of all significant meaning.

The Act was not directed towards the abstract goal of purifying the "channels" of interstate commerce. As was stated in *United States*

v. *Sullivan*, 332 U. S. 689, 696, "the Act as a whole was designed primarily *to protect consumers* from dangerous products" (italics added). This precise contention was discussed by the Court of Appeals for the Seventh Circuit in *United States* v. *Lee*, 131 F. 2d 464, 466:

> It [the Act] was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

The Food and Drug Administration of the Federal Security Agency, which has responsibility for enforcement of the Act, has placed an authoritative administrative construction on these provisions. Its Regulation (set forth in the Appendix, p. 45) provides:

> Labeling includes all written, printed, or graphic matter accompanying an article *at any time* while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. [Italics added.] [1]

[1] This common-sense construction is reinforced by the amendment made to the Act by Public Law 749, 80th Cong., 2d Sess., approved June 24, 1948. The amendment, though inapplicable to the present case, inserted in Section 304 (a) immediately after the words "when introduced into or while in interstate commerce" the following: "or while held for sale (whether or not the first sale) after shipment in interstate

B. ADVERTISING MATTER IS NOT EXCLUDED FROM THE DEFINITION OF LABELING

Although it did not expressly so hold, the court below indicated doubt that the leaflets could properly be considered labeling for the machines because it thought the leaflets were more in the nature of advertising (R. 181–182).

The fact that the leaflet "The Road to Health" has some of the characteristics of advertising does not exclude it from the l a b e l i n g definition. Nothing in the Act suggests that labeling and advertising are mutually exclusive. An item of printed matter may at once serve the dual purpose of advertising and labeling. In the *Kordel* case, the court said (No. 30, R. 463):

> * * * labeling and advertising are not mutually exclusive, and the same matter may serve both purposes.

In *United States* v. *Research Laboratories*, 126 F. 2d 42, 45 (C. C. A. 9), certiorari denied, 317 U. S. 656, the court said:

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commerce." This amendment was deemed necessary because of the decision in *United States* v. *Phelps-Dodge Mercantile Co.*, 157 F. 2d 453 (C. C. A. 9), certiorari denied, 330 U. S. 818. In that case it was held that the law did not authorize seizure of a food which became contaminated while stored in a warehouse where it was placed after its interstate journey. The committee reports on the amendment state that the *Phelps-Dodge* decision "resulted in frustration" of the intent of the 1938 Act and "thus revealed a serious defect in the present law." See H. Rep. No. 807, 80th Cong., 1st Sess., p. 2; S. Rep. No. 1221, 80th Cong., 2d Sess.

> Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. This assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying an article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

Congress' exclusion of labeling from the definition of "false advertisement" in the Federal Trade Commission Act, 15 U. S. C. 55 (a), implicitly recognizes that labeling and advertising matter are overlapping terms. The definition reads in part:

> The term "false advertisement" means an advertisement, other than labeling, which is misleading * * *."

This definition and that of "labeling" in Section 201 (m) clearly indicate that advertising which serves the purpose of labeling, as do the circulars here, is within the reach of the Federal Food, Drug, and Cosmetic Act.

The leaflets here were prepared by the respondent, and were supplied by him to the consignee for the purpose of explaining to prospective purchasers, renters, and patients the usefulness of

the device and how it is employed in the diagnosis, cure, mitigation, and treatment of various diseases. The label of the device bore only "U. S. Patent Sinuothermic Trade Mark" (R. 20). Obviously, such a label does not explain the purposes for which the device was intended to be used, but the leaflet did contain that information in elaborate detail. Thus, the leaflets were intended to and did serve the purposes of labeling equally as much as if they had been physically attached to the machines. Without the extravagant claims made in the leaflets it is doubtful that the devices could be rented or sold or that the services of the machines could have been sold to patients.

If drugs and devices are not subject to the prohibition of the Act because printed "advertising" matter relating to them is sent separately, then unscrupulous or disingenuous distributors have a made-to-order plan to evade the Act. And the practice of shipping printed matter separately from drugs and devices is wide-spread.*

* Since the enactment of the law in 1938, it has become a common practice among those intent on evasion to ship articles separately from leaflets, circulars, and booklets containing false claims made to further the distribution of such articles. The Food and Drug Administration has been equally active in contesting these evasive schemes. Between the date of the *Research Laboratories* opinion, February 24, 1942, and May, 1948, 870 Notices of Judgment have been published in cases involving drugs and devices actionable under the Federal Food, Drug, and Cosmetic Act. A survey of the cases reported in those Notices of Judgment reveals that "ac-

The court below suggests that testimonials and case histories cannot properly be regarded as labeling. The answer to this suggestion was made in *United States* v. *John J. Fulton Co.*, 33 F. 2d 506, 507 (C. C. A. 9):

> * * * if, as is alleged, the drugs are worthless, the proprietors cannot escape re-

---

companying" printed matter has been involved in 348 cases. This figure includes cases in which the literature alleged to have accompanied the goods in interstate commerce was not actually shipped with the goods, as well as those where there was physical accompaniment. Of the 348 cases, 262 were seizures, 81 criminal actions, and five were suits for injunctions.

One hundred and forty-one cases, out of the total of 348, were clearly concerned with situations where the alleged accompanying labeling traveled in interstate commerce either before or after the goods or by a different means of transportation. One hundred and four of the 141 cases were seizure actions, 36 involved criminal prosecutions, and one was a suit for injunction.

The following table indicates the disposition of the 141 cases mentioned above:

SEIZURES		CRIMINAL ACTIONS	
Default Decree	74	Plea—Guilty—J/Govt	18
Consent Decree	25	Plea—Nolo—J/Govt	16
Contest—Judgment for Claimant	1	Plea—Not Guilty—J/Defendant	1
Contest—Judgment for Govt	4	Plea—Not Guilty—J/Govt	1
TOTAL	104		36

INJUNCTION

Granted 1

The two cases in which judgment was adverse to the Government were decided on grounds other than accompaniment.

> sponsibility by hiding behind the phrase "the doctors say." Couched in such language undoubtedly the printed matter makes a more persuasive appeal to the credulity of sufferers from these diseases than if the representations thus implied were made directly upon the authority alone of the proprietors, and for that reason they are not less, but more, obnoxious to the law.

This Court said in *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116:

> There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of *caveat emptor* should not be relied upon to reward fraud and deception.

Accord: *Donaldson* v. *Read Magazine*, 333 U. S. 178, 188–189.

The only cases known to the Food and Drug Administration in which the accompaniment question was decided adverse to the Government, *Alberty* v. *United States*, 159 F. 2d 278 (C. C. A. 9), and the instant case, are as yet unreported in Notices of Judgment.

The type of literature which appeared in the accompanying labeling cases most frequently was that termed "circulars." Other kinds of written material alleged to have constituted accompanying labeling were leaflets, booklets, books, catalogs, display cards, pamphlets, placards, letters, and printed sheets.

Plainly, therefore, in a practical, every-day sense, the machines were "accompanied" by the leaflets. A person who read the leaflet would be misled to the same extent whether or not it traveled in interstate commerce in the same train, or at the same time, or over the same route, as the machine. To hold that, in such a situation as this, the Act affords no protection would merely provide a ready means for evasion of the salutary purposes of this law.

II

THE EVIDENCE AMPLY SUPPORTS THE TRIAL COURT'S FINDINGS AS TO THE FALSITY OF THE REPRESENTATIONS REGARDING DIAGNOSTIC CAPABILITIES OF THE DEVICE; THE GOVERNMENT IS THEREFORE ENTITLED TO A DECREE OF CONDEMNATION, EVEN ASSUMING THAT EVIDENCE AS TO THERAPEUTIC VALUE WAS ERRONEOUSLY EXCLUDED

The leaflets contain representations for the capabilities of the devices in two distinct fields—diagnostic and therapeutic. The Statement sets forth some of the claims of diagnostic capabilities (*supra*, pp. 6–8). With respect to the diagnostic claims, the trial court found that they represented that the devices would register the exact nature of any disease and would diagnose disease, and further found that the principles on which the machines were claimed to operate were impossible of practical application with the instruments. (R.

165–166, Findings 4–5, 7). These findings of fact do not appear to be challenged.*

The evidence which the Court of Appeals held was improperly excluded related not to the representations of diagnostic capacity but only to the representations of therapeutic value. The evidence excluded was of two types: (1) testimony of respondent's lay patients as to their condition before and after treatment with Sinuothermic machines; (2) testimony of respondent as to his diagnoses of their conditions made with the machine. As to the first type of evidence, the trial court ruled that such testimony was incompetent opinion evidence or hearsay. As to the second type of evidence, it is clear from the record that it was offered as a basis on which to show curative capabilities of the machine. (See R. 158, 160–163.) The court excluded this evidence because there was uncontradicted testimony, including testimony from the respondent, that the machine could not diagnose any specific condition. Thus, the misrepresentations as to diagnostic capacity were established in part by respondent's own admissions. His testimony was that the machines—even the ones that had meters—would not specifically diagnose what the patient's ailment

* The meaning conveyed by language used in labeling is a question of fact. *Bradley* v. *United States*, 264 Fed. 79 (C. C. A. 5); *Hall* v. *United States*, 267 Fed. 795 (C. C. A. 5); *United States* v. *John J. Fulton Co.*, 33 F. 2d 506 (C. C. A. 9); *United States* v. *7 Jugs* * * * *Rakos*, 53 F. Supp. 746, 759–760 (D. Minn.).

was (R. 129–130). He said that the device "merely locates when there is something wrong." The Government's evidence was overwhelming that the machines could not do even that. The Court of Appeals pointed out that the respondent's testimony "only claimed the machine to be an aid in diagnosing." His testimony was that the machine "only located the spot where the abnormal tissue was" after which "it was then a matter of judgment as to what the disease was" (R. 182).

The labeling claims are irreconcilable with this testimony. They assert that the machine "leaves out guess work"; that it "registers exactly and never makes a mistake"; and that it removes the necessity of having "someone guess at what your ailment is." See p. 7, *supra*. Respondent's testimony implicitly admitted that those claims are falsehoods. The Government's evidence gave them the lie explicitly. The representations as to diagnostic capacity were false and on this phase of the case alone, the Government was entitled to a decree of condemnation. Any error in the exclusion of evidence which did not disprove the making of such misrepresentations would not defeat the Government's right to condemnation.

Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are both false and misleading in all respects. Petitioner is entitled to a decree of condemnation if it shows that any one of the various claims made in the labeling is

either false or misleading in any particular. Section 502 (a); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C. C. A. 6); *United States* v. *Six Dozen Bottles* * * * *Kuriko*, 158 F. 2d 667, 669–670 (C. C. A. 7); and *United States* v. *One Device* * * * *Colonic Irrigator*, 160 F. 2d 194, 200 (C. C. A. 10).

The evidence that was excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158–163). The Court of Appeals concluded that the evidence from respondent as to his diagnoses was erroneously excluded because he used the machines only as an aid in diagnosing, and that the patients should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183). The admission of the evidence within those limits would have had no bearing upon the capabilities of the machines as instruments for diagnosing disease.

Since it appears from the undisputed testimony and from the admissions of the respondent that the machines are incapable of diagnosing specific conditions, and since the machines were represented as having such diagnostic capabilities, petitioner is entitled to a decree of condemnation if it prevails on the "accompaniment" issue, irrespective of whether the court below was correct in holding other evidence relating to the curative value of the machines improperly ex-

cluded. The respondent was not prejudiced by the exclusion of this evidence and the ruling of the trial court is not reversible. *Ross Lumber Co.* v. *Hughes Lumber Co.,* 264 Fed. 757, 760 (C. C. A. 5), certiorari denied, 254 U. S. 635; *Nalbantian* v. *United States,* 54 F. 2d 63, 64 (C. C. A. 7), certiorari denied, 285 U. S. 536; *Jennings* v. *United States,* 73 F. 2d 470, 471 (C. C. A. 5). Accord: *Holloway* v. *Dunham,* 170 U. S. 615, 618.

Furthermore, the decision below on the "accompaniment" issue calls for a dismissal of this libel. If the court below was wrong on that point but correct in reversing the judgment because of the exclusion of evidence, respondent would at most be entitled to a new trial at which the excluded evidence could be admitted. We believe, however, that the court below is in error on both points, and that the judgment of the district court is correct.

CONCLUSION

For the reasons stated it is respectfully submitted that the judgment of the Court of Appeals should be reversed, and that of the district court reinstated.

PHILIP B. PERLMAN,
Solicitor General.
ALEXANDER M. CAMPBELL,
Assistant Attorney General.
PHILIP ELMAN,
Special Assistant to the Attorney General.
WILLIAM W. GOODRICH,
BERNARD D. LEVINSON,
Attorneys, Federal Security Agency.

SEPTEMBER 1948.

APPENDIX

STATUTE AND REGULATION INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), and regulations issued thereunder follow:

SEC. 201. For the purposes of this Act—

* * * * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

* * * * *

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article;

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but, if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *

REGULATION

21 C. F. R. Cum. Supp. §2.2 Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

U. S. GOVERNMENT PRINTING OFFICE: 1948

In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 13

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

SUPPLEMENTAL MEMORANDUM FOR THE UNITED STATES

Respondent states in his brief (p. 8) that the Government "reluctantly admits that the Circuit Court of Appeals was correct in holding the District Court in error" for excluding the testimony offered by respondent as to (1) the benefits claimed to have been received by various patients through use of the Sinuothermic device, and (2) respondent's alleged success in diagnoses and treatments made with the machine (see R. 162–163). Since this statement of the Government's position is not accurate, we are submitting this supplemental memorandum for the purpose of

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avoiding any misunderstanding which might otherwise result.

When this testimony was offered at the trial, Government counsel objected on several specific grounds. This objection was sustained by the district court (R. 163). The Government contended in the court below that this ruling by the trial court was entirely proper, and we have in no respect receded from that position. The Government's position is that, even if it be assumed *arguendo* that the proferred testimony was erroneously excluded, the decree of condemnation entered by the district court was nevertheless correct. The Government was entitled to such a decree if any of the various claims in the labeling was false or misleading. The evidence as to the falsity of the diagnostic claims made for the machine was overwhelming, and included respondent's own admissions (see R. 129–130, 182). The excluded evidence related only to the claims of therapeutic or curative value (R. 158–163). Consequently, even if it be assumed that the exclusion was erroneous, such error could not have been prejudicial.

In these circumstances, the petition for certiorari filed by the Government stated (page 12, note 3) that "Error is not assigned as to the rulings below with respect to the exclusion of evidence by the trial court." This statement was made in order to limit the review by this Court

to the issue of statutory construction involved, and not, as respondent believes, to constitute an admission that error had been committed by the district court.

Respectfully submitted.

PHILIP B. PERLMAN,
Solicitor General.

OCTOBER 1948.

U. S. GOVERNMENT PRINTING OFFICE: 1948

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NO. 547 / 3

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1947 48

UNITED STATES OF AMERICA,

PETITIONER

versus

FRED URBUTEIT, Claimant of 16 Articles of Device More or Less, Labeled "SINUOTHERMIC", etc.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE RESPONDENT

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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1947

NO. 577

UNITED STATES OF AMERICA,

PETITIONER

versus

FRED URBUTEIT, Claimant of 16 Articles of Device More or Less, Labeled "SINUOTHERMIC", etc.

BRIEF FOR THE RESPONDENT

For the purpose of brevity this brief will omit repetition of and changes in the recitations made in the Petition and Brief of Petitioner, but the Court is requested to consider the statement of the case contained in the opinion of the Circuit Court of Appeals (R. 179) as a fair and accurate summary of the matters of fact and law that are involved.

Summary of Argument:

Respondent contends that the petition should not be granted for the following reasons:

1. The statutory construction made by the Circuit Court of Appeals is correct.

   (a) The language is susceptible to no other interpretation.

   (b) The explanation given to a Congressional Committee and quoted by Petitioner on Page

17 of its Petition shows that Congress was not informed of the possibility of any such construction as is now contended for by Petitioner.

2. The finding of the Circuit Court of Appeals that as a matter of fact the leaflets involved did not constitute "labeling" in their very nature is correct.

3. No misrepresentations as to the diagnostic capacity of the "Sinuothermic" device were admitted or established as contended by Petitioner.

4. A proceeding for seizure and condemnation is limited by Section 304 (a) of the Food, Drug and Cosmetic Act to "Any article of food, drug, device, or cosmetic that is adulterated or misbranded *when introduced into or while in interstate commerce.*"

5. Certiorari should not be granted in this case because the opinion of the Circuit Court of Appeals for the Fifth Circuit conflicts with the palpably erroneous holding of the Seventh Circuit on the meaning of "accompanying", but that error should be corrected in the case of United States vs Kordel. (See Appendix to Petition)

ARGUMENT

1. THE STATUTORY CONSTRUCTION MADE BY THE CIRCUIT COURT OF APPEALS IS CORRECT.

(a) Both the opinion of the Circuit Court of Appeals (R. 180) and the Petition (page 3) quote the parts of the Federal Food, Drug and Cosmetic Act involved in this case. That part of Sec. 201 defining "labeling" is here quoted also:

"(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Mr. Webster defines "accompany" as meaning "to keep company with; escort; join in movement or action." The Federal Food, Drug and Cosmetic Act relates to the shipment in interstate commerce of foods, drugs, cosmetics and therapeutic devices, so it is obvious that "accompanying" ir the statute means "accompanying in interstate commerce". It is a cardinal rule of statutory construction that ordinary words must be given their ordinary and accepted meaning and "accompanying" cannot be stretched so as to eliminate the time element and other factors necessarily implied in the connotation of the word and without which it would be meaningless.

The Congress is composed of people who certainly have a better than average command of both written and spoken English, and many are exceptionally well versed in the choice of words and their proper usage, and it is an insult to the intelligence of the members of Congress to say that by their language used in the quoted statute they meant anything like what the Petitioner claims they meant. As Judge Sibley remarked to Petitioner's counsel during his argument before the Circuit Court of Appeals—"if your law is not broad enough get a new one but don't try to stretch it".

(b) On page 17 of the Petition is quoted the statement made by Walter G. Campbell, then Chief of the Food and Drug Administration, made to a Congressional Committee in explanation of the definition when the Committee of the Seventy-Third Congress, Second Session, was considering the Food, Drug and Cosmetic Act. There is nothing whatever in that language to indicate that Mr. Campbell even had in mind the possibility of

such a construction as is now contended for by Petitioner. It is clear that Mr. Campbell was intent on having the law changed so that it would not only have "control over those statements that are attached to or that accompany the package in the form of circulars" but would include "all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug, or cosmetics". Please note that he is talking about the form of the material—"form of circulars" and "any form whatever" and not the manner of accompaniment.

The abortive attempt of the Administrators of the Act to seize power not granted to them and attribute meanings to its language that are illogical and that were never intended is spotlighted by the record of Mr. Campbell's statement to Congress.

2. THE FINDING OF THE CIRCUIT COURT OF APPEALS THAT THE LEAFLETS DID NOT CONSTITUTE LABELING IS CORRECT.

Petitioner has argued at considerable length and has removed from their context and quoted a number of statements contained in the leaflet involved in this case in a vain effort to show that the leaflet constitutes labeling of the Sinuothermic device. The opinion of the Circuit Court of Appeals (R. 181) deals with the nature of this leaflet and states that "It may be doubted that the printed matter is in its nature a labeling for the machines". The Court there deals with a matter of fact —facts peculiar to the instant case—and not with the construction of a statute, and its analysis and statement of the facts is fair, sensible and sound, and its conclusion, based on the facts, is planted on a firm foundation and cannot easily be assailed.

3. NO MISREPRESENTATIONS AS TO THE DIAGNOSTIC CAPACITY OF THE "SINUOTHERMIC" DEVICE WERE ADMITTED OR ESTABLISHED AS CONTENDED BY PETITIONER.

Petitioner, in contending that it would be entitled to a decree of condemnation IF the leaflets were labeling and IF they accompanied the devices and IF the statements in the leaflets contained false representations as to the therapeutic value of the device, plants its contention on a false premise—that the evidence which the Circuit Court of Appeals held was improperly excluded by the District Court did not relate to the diagnostic capacity of the machines. Now the nature of the evidence excluded can be learned from one place only and that is the proffer, objections to which the District Court sustained. (R. 162) In that proffer it was plainly stated that Claimant offers to testify as to his diagnosis with the use of the Sinuothermic machine and otherwise . . . ., so it is readily apparent that the contention of Petitioner is nothing but wishful thinking.

The effort of Petitioner to attribute to the word "diagnosis", and statements concerning diagnosis, meanings and imputations that no sensible person would ever seriously think of, would be laughable if not involved in such a serious matter. There are many mechanical instrumentalities used in diagnosis by the several branches of the healing art, and some of them do remarkable things, but they are useless without the human personality and the trained mind that can draw conclusions from the factors indicated. As simple a thing as an electric meter "registers exactly"—but how many people who pay electric bills can tell just what it registers or what it means. Its simply an aid to the electric company in making its diagnosis of the customer's liability, and a human mind is required to read the meter and calculate

the liability. We say that we were examined or our case was diagnosed by or with an x-ray, or an electro-cardiograph or something else, and that the x-ray showed so and so or the electro-cardiograph reading showed such and such a condition, but we don't mean to intimate that anything was done without the intervention of a trained mind and no one would think of attributing any such meaning to our statement.

The argument contained in the petition on this point is puerile. The writer of this brief knows that the Solicitor General did not originate it. This writer heard the idea hinted at by an attorney for the Food and Drug Administration in Washington a while back and supposes that the Solicitor General can hardly be expected to sift all the chaff out of the wheat in the cases that are sent to him.

4. A CONDEMNATION PROCEEDING IS LIMITED TO ANY ARTICLE MISBRANDED WHEN INTRODUCED INTO OR WHILE IN INTERSTATE COMMERCE.

The Federal Food, Drug and Cosmetic Act has numerous prohibitive provisions—some civil and some criminal in their nature—and they are applicable under varying conditions. The authority for and the conditions surrounding the institution of a condemnation proceeding such as is involved in this case is contained in Section 304 (a) of the act and that section is quoted on page 3 of the Petition. To come within that section an article must be adulterated or misbranded *when introduced into or while in interstate commerce.* Now it is clear that the devices and the leaflets were never in interstate commerce at the same time so by no stretch of the imagination can it be said that the devices were misbranded when introduced into interstate commerce or

while in interstate commerce, and this fact remains true regardless of whether or not the leaflets were labeling and false. There simply was no statutory authority for this proceeding in the first place as by Petitioner's own testimony the alleged misbranding could not have taken place until after the devices had passed out of interstate commerce and come to rest and been put to use in Ohio.

5. CONFLICT BETWEEN TWO CIRCUITS SHOULD NOT CAUSE CERTORARI TO BE GRANTED EXCEPT IN THE CASE WHERE THERE IS ERROR.

In petitioning for a writ of certiorari in this case Petitioner asks this Court to take jurisdiction because there is a conflict in the opinion of the Circuit Court of Appeals for the Fifth Circuit in this case and the opinion of the Circuit Court of Appeals for the Seventh Circuit in the case of United States vs Kordel, not reported. (See appendix to the Petition for the opinion). It is the understanding of this writer that a petition for certiorari in the Kordel case has or will in due course be filed.

The Kordel case is a criminal proceeding—this one is civil. The conflict is in the construction of that part of the statute that uses the word "accompanying". On that point one Court is clearly right and the other definitely wrong. There is no middle ground and there is no reconciliation of the two opinions. It is not a very complicated question. The Solicitor General has presented his argument in this case and there is nothing more that he can offer on the point. If this Court agrees with the Circuit Court of Appeals for the Fifth Circuit there is no necessity for certiorari in this case and the error of the Circuit Court of Appeals for the Seventh Circuit can be corrected in the Kordel case in due course.

CONCLUSION

This brief has not dealt with the real merits of respondent's case because the questions before this Court are principally of a technical nature. The Petition by inference and comment here and there attempts to give the impression that Respondent is an unscrupulous crook and his device a fraud. The facts and the ins and outs of the case cannot be gone into here but because of the attempted aspersions this writer is impelled to call the attention of the Court to the fact that medical history discloses that one after another of the progressive doctors and scientists of days gone by were condemned by the intrenched profession of their day, and that usually there was a ready and willing government or agency that jumped when the string was jerked. Never was there a fair or scientific study but always the same old story—the "expert opinions" of those who knew so much they were unwilling to be shown. Unwilling to investigate—unwilling to look—unwilling to learn—but eager to testify and persecute. That is the record in this case—both the actual and official Court record—and the record that is not a part of this proceeding but the history of Respondent's experiences.

Respondent respectfully asserts that there is no error in the opinion of the Circuit Court of Appeals for the Fifth Circuit and consequently no reason for the issuance of a writ of certiorari to that Court.

H. O. PEMBERTON,
Attorney for Respondent

February 1948.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1948.

No. 13

UNITED STATES OF AMERICA,
Petitioner,

vs.

RED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS, FIFTH CIRCUIT.

BRIEF FOR THE RESPONDENT.

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FRED URBUTEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS, FIFTH CIRCUIT.

BRIEF FOR THE RESPONDENT.

OPINION BELOW.

The opinion of the Circuit Court of Appeals (R. 179-183) is reported at 164 F. 2d 245.

JURISDICTION.

The judgment of the Circuit Court of Appeals was entered on November 7, 1947 (R. 183). The petition for a writ of certiorari was filed February 6, 1948, and was granted April 19, 1948 (R. 185). The jurisdiction of this Court was invoked by petition under Section 240(a) of the Judicial Code as amended.

STATEMENT OF THE CASE.

Petitioner, the United States of America, filed a libel for condemnation in the United States District Court, Southern District of Ohio, alleging that the therapeutic devices sought to be condemned were misbranded when introduced into and while said devices were in interstate commerce (R. 1).

Dr. Fred Urbuteit of Tampa, Florida, filed a claim for a number of the devices (R. 5) and the case was transferred to the Northern District of Florida (R. 8).

The libel was amended (R. 11) and answered (R. 10), and the case tried without a jury (R. 15).

The issues framed by the pleadings in the lower court were whether or not the leaflet alleged to be a "labeling" of the devices, did in fact constitute a labeling under the Federal Food, Drug, and Cosmetic Act; and whether or not the statements in the alleged labeling are false and misleading.

The District Judge excluded evidence offered by the claimant Urbuteit (R. 159-163) and found for the libellant on those issues (R. 163). A decree of condemnation was entered (R. 168) and a motion for a new trial was filed by claimant (R. 169), but no brief or oral argument on the motion was permitted by the District Judge who promptly entered an order denying the motion (R. 170). From this order and the decree of condemnation the claimant Urbuteit appealed (R. 174).

The Circuit Court of Appeals reversed the District Court, and for a fair and concise further statement of the case the Court is requested to read the opinion of the Circuit Court of Appeals (R. 179-183).

A summary of the testimony in the District Court follows:

SUMMARY OF TESTIMONY.

Libellant's Witnesses:

Sidney Weissenberg (R. 16-23) testified that as an inspector for the United States Food and Drug Administration he inspected the devices proceeded against on the premises of Dr. J. J. H. Kelsch in Cincinnati, Ohio, making three visits—August 22, Sept. 5 and Sept. 28, 1945. On Sept. 5, 1945, he found four copies of a leaflet called "The Road to Health". Two copies were on Dr. Kelsch's desk and two were in his desk drawer.

O. O. Rowland (R. 23-35), trace clerk for the Railway Express Agency, produced shipping records showing shipments from Tampa, Florida, by Dr. Urbuteit or his agent to Dr. Kelsch in Cincinnati, Ohio, on the following dates: July 25, 1945; August 14, 1945; August 18, 1945; September 21, 1945. Appellant admits that these shipping dates are correct and represent the shipment of Sinuothermic devices to Dr. Kelsch. No leaflets were contained in these shipments, however, and no claim that they were has been made by the Government.

Dr. J. J. H. Kelsch (R. 25-35) testified that he is a Chiropractor and Naturopath practicing in Cincinnati, Ohio; that he went to Tampa and received instruction from Dr. Urbuteit in the use of the Sinuothermic Device, arranged for the purchase of some and rental of other of the devices, and a supply of the leaflets, "The Road to Health" and later received the devices in Cincinnati. After the devices had been received he received a bulk shipment of the leaflets—he could not remember when except that it was sometime around September. He mailed out the leaflets to his patients and used the devices in his practice. On direct examination he described very briefly the general manner in which the device is used but was not per-

mitted to testify as to the result obtained when asked that question on cross-examination. He testified that he received the devices as a practicing physician for use in his practice and not as a seller or vendor of therapeutic devices but that he sold one to a family who took treatments from him but who lived in Kentucky, and wanted one so their treatments could be continued at their home.

Mrs. Joseph H. Kelsch (R. 35-36) testified simply to the fact that she signed the express records previously introduced and received the devices which were later seized.

W. C. Osterbrock, (R. 36-49) professor of Electrical Engineering at Ohio State University testified that he had examined the devices and described their construction. The substance of his testimony was that the devices by means of a potentiometer and a transformer reduced the current from the standard electric 115 volt A. C. lighting circuit—that there are many and varied forms of transformers and that from his examination he could not tell how the transformer in the device was wound and constructed. Condition of the skin, moisture, pressure and other factors vary the resistance of the human body to the passage of an electrical current. Volt and ampere meters (some of the devices having such meters) are not accurate in the lower 20% of their full scale reading. His tests or examination of the device was limited to a measurement of the current by his laboratory meters and a device known as an oscillograph which shows the wave form of the current.

Daniel R. McMillan, Jr., (R. 49-53) Professor of Physics at Emory University testified briefly, there being nothing in his testimony that was not included by Professor Osterbrock.

John Haldi, (R. 53-70) Professor of Physiology at Emory University testified rather extensively and willingly about himself and his experiments. He managed to kill several

dogs by fastening the electrodes of the device to them and giving them a heavy load of electrical energy. He found that when he first turned on the current their respiration and blood pressure was affected and that it then returned to normal. He was afraid to try it on human beings other than to simply have them hold the electrodes and feel a slight tingle. He did not see how electrical energy could bring about any physiological changes in the human body or how a condition could be judged by the resistance to a current.

Seven doctors of medicine came to the witness stand one after the other (R. 70-115). None of them except one had ever so much as seen the device before he came to court. None of them were shown to be specialists in any form of electrotherapy, except that one of them is a Roentgenologist, confining his practice to the use of the X-ray. They all admitted that they knew nothing about the device but all were quite sure it was no good. One of them told of two experiments made by him with the device—one on an advanced tubercular patient and the other on a cancerous leg. The nature of his superficial tests as disclosed by his testimony and his testimony relative thereto cannot be fully appreciated without a reading of that portion of the record. (R. 113-115.)

Claimant's Witnesses:

As the first witness for the Claimant Mr. James C. Pearson, (R. 117-119) Chief Inspector of the Atlanta Station of the Food and Drug Administration, was called for the purpose of showing that his men had interviewed large numbers of patients of Dr. Urbuteit and had investigated the result of their treatments with the Sinuothermic device and that Dr. Urbuteit, in the office of the Pure Food and Drug Administration in Atlanta had offered full cooperation and requested the cooperation and participa-

tion of the Administration in making complete and thorough clinical tests of the Sinuothermic device. On the objection of Libellant's attorneys that such testimony would be irrelevant the Court did not require Mr. Pearson to answer the questions.

Dr. Fred Urbuteit, Claimant, (R. 119-158) testified as to his education and training and practice as a Naturopathic Physician, and his experiments over many years in an effort to find a form of electrical energy that would amplify the function of the various parts of the human body. During the course of his experiments and search he developed a serious arthritic condition and while in its last stages with his body highly sensitized he was able to feel the direct waves from the instrument without any application of pads or any sort of contact with his body, and with the aid of an associate working under his direction he was able to make changes in it until the effect of the wave on his body was soothing rather than coarse and irritating. From this point the part of the instrument necessary to pick up the wave or energy and apply or direct it to any particular part of the body in the necessary volume was developed. The instrument went through various stages of mechanical construction, its volume being controlled mechanically before potentiometers were made, until its present mechanical form was developed. He described his own physical condition and the results obtained from his treatments of himself with the device and described his examination and treatment of each of the persons mentioned in the leaflet "The Road to Health", the statements in which were by the Libellant alleged to be false and misleading, and stated that each of the statements therein was true.

Dr. Urbuteit described the way the Sinuothermic device is used in the diagnosis of the condition of and the treatment of abnormal conditions in the human body.

This general description is in addition to his statements describing the specific cases mentioned in the leaflet and appears at pages 126-130 of the record. He stated that he used various accepted methods of diagnosis in addition to the Sinuothermic device but that he had found after long experience that when the Sinuothermic device located where something was wrong, the chemical or other tests that might be necessary to determine the name of the ailment would not be necessary to the treatment and the patient getting well. He stated that he estimated the number of people treated by him with the device to be about ten thousand and had in the Court room a trunk containing thousands of cards, each of which was the record of his diagnosis and treatment of a different patient; that no person had ever suffered any injury or adverse effect from the device.

After the general examination of Dr. Urbuteit his attorney, the writer of this brief, stated that he proposed to interrogate Dr. Urbuteit as to his diagnosis and treatment of a number of witnesses present and then interrogate those witnesses as to their condition as known to them and their treatment by Dr. Urbuteit with the Sinuothermic device.

On objection of the attorney for Libellant the Court refused to permit Dr. Urbuteit to testify as to his diagnosis of Mrs. J. W. Porter (R. 158-159).

Mrs. J. W. Porter was then called as a witness and stated that she took treatments from Dr. Urbuteit with the Sinuothermic device about nine years before. On objection of Libellant's attorney the Court refused to permit her to testify as to her condition as known to her (R. 159-161).

Proffer of the testimony of approximately thirty witnesses as to their treatment by Dr. Urbuteit with the Sinuothermic device and their condition as known to them be-

fore, during and after the treatment was then made by Claimant's attorney, together with a proffer of testimony by Dr. Urbuteit as to his diagnosis of the condition of such witnesses with the use of the Sinuothermic device and otherwise, his treatment of such witnesses with the Sinuothermic device and the results obtained from such treatments. On objection of Libellant's attorney the Court refused the proffer (R. 162-163).

The Court then, without hearing any argument or summary and without himself making any summary or explanation, stated that "The Court finds for the Government. The United States Attorneys will prepare an appropriate decree and present the same to the Court" (R. 163).

SPECIFICATION OF ERRORS.

The Petitioner (the United States) reluctantly admits that the Circuit Court of Appeals was correct in holding the District Court in error for excluding testimony proffered by Claimant (Urbuteit, the Respondent here), but tries to claim that the excluded testimony would not refer to use of the Sinuothermic device in diagnosis and that there was substantial evidence to support a decree of condemnation for misbranding as regards the diagnostic use of the device, and that the Circuit Court of Appeals erred in not so holding.

The principal alleged error that Petitioner seems to urge, however, is the holding by the Circuit Court of Appeals that the leaflets the Petitioner calls "labeling" did not accompany the devices in interstate commerce and, therefore, did not constitute "labeling"—and the expression of doubt by the Court that the leaflets were in their nature "labeling" even if they had accompanied the devices in interstate commerce.

ARGUMENT.

SUMMARY: As to the first of the above stated alleged errors Respondent maintains that there was no substantial evidence to sustain a finding that there was a misbranding as regards the diagnostic use of the device—regardless of whether or not the leaflets actually constituted labeling—and further maintains that the excluded testimony would have dealt definitely and extensively with the use of the device in diagnosis and the results obtained.

As to the second of the alleged errors, it is the contention of Respondent that the leaflets were never in interstate commerce at the same time the devices were—and not even the Petitioner claims that they were—and for this reason they did not accompany the devices and consequently were not labeling of the devices when introduced into or while in interstate commerce. It is the further contention of Respondent that it is clear from a reading of the leaflet that it is not in its nature a labeling of the devices and would not have been labeling if the leaflets had been packed in the boxes with the devices.

No Misrepresentations as to the Diagnostic Capacity of the "Sinuothermic" Device Were Admitted or Established as Contended by Petitioner.

Petitioner has quoted isolated excerpts from the leaflet and testimony in an effort to show that the leaflet contained false statements as to the value or use of the Sinuothermic device in diagnosis.

The testimony has already been summarized in this brief and by reference to that summary or the complete transcript in the record the Court will see that the evidence introduced to support the allegations of falsity was

composed entirely of the opinions of doctors who were qualified simply as doctors and not experts or specialists in the field of electrotherapy. Each and every one of them admitted that he did not know anything about the Sinuothermic device. Their opinion was based solely on the fact that they simply had no knowledge of any electrical device that would be effective as claimed. The writer of this brief is a lawyer licensed to practice in the State of Florida. He has never practiced in any other state. If asked a question about some point of law in another state he might feel fairly sure that it was so and so because he knew nothing to the contrary, but his opinion on the point would not be worth anything and he would not have the gall to hold himself out as qualified to answer the question. The witnesses in this case, however, were not bothered by such an inferiority complex.

The Food and Drug Administration was, by the answer or claim of Dr. Urbuteit filed in this case (R. 7) offered co-operation and invited to make thorough clinical tests of the Sinuothermic device. This writer personally called on the head of that agency in Washington and urged such tests, but to no avail. The flimsy evidence offered, therefore, was by choice and not necessity.

As against this sort of testimony Dr. Urbuteit told of developing the device, how it works, of his many years of practice with it and the results obtained in both diagnosis and treatment. He went through the leaflet from one end to the other and told of each case or incident related therein, stated who the people were and swore that the statements were true. A number of those people and many others were waiting outside the Court room to give factual testimony to support his statements. The Food and Drug Administration had interviewed most of those people and many others who had taken Sinuothermic treatments. The Administration knew to what other

doctors many of those people had been—but chose to rely on the testimony of a group of doctors whose opinions, or whose testimony at least, would not in any way be based on experience or knowledge of specific cases.

Petitioner, in contending that it would be entitled to a decree of condemnation IF the leaflets were labeling and IF they accompanied the devices and IF the statements in the leaflets contained false representations as to the therapeutic value of the device, plants its contention on a false premise—that the evidence which the Circuit Court of Appeals held was improperly excluded by the District Court did not relate to the diagnostic capacity of the machines. Now the nature of the evidence excluded can be learned from one place only and that is the proffer, objections to which the District Court sustained. (R. 162.) In that proffer it was plainly stated that Claimant offers to testify as to his diagnosis with the use of the Sinuothermic machine and otherwise * * *, so it is readily apparent that the contention of Petitioner is nothing but wishful thinking.

In this connection it might be interesting to take note of that word "diagnosis". 12 *Words and Phrases* 375 refers us to a couple of cases that state rules or principles that any person of average intelligence and experience is familiar with. "At the best, diagnosis is little more than a guess enlightened by experience"—*Swan* v. *Long Island R. Co.*, 29 NYS 337; and "A practitioner has diagnosed a case when he makes such examination of the patient as he regards as sufficient to indicate to him the cause of the trouble and its proper treatment", *People* v. *Zinke*, 7 NYS 2d 941. Every member of the Court probably knows of a number of people who have gone from one doctor to another and gotten a different diagnosis each time. Appellant submits that the best proof of the accuracy of any system or means of diagnosis and the

effectiveness of any treatment is the record of repetitive cases in which the diagnosis is made, the treatment is administered and the patient gets well. That is the evidence that the Court would not admit simply because several doctors of another faith had no experience with or knowledge of a device used by the doctor testifying in his diagnosis and treatment and did not believe it would be effective for diagnosis.

The effort of Petitioner to attribute to the word "diagnosis", and statements concerning diagnosis, meanings and imputations that no sensible person would ever seriously think of, would be laughable if not involved in such a serious matter. There are many mechanical instrumentalities used in diagnosis by the several branches of the healing art, and some of them do remarkable things, but they are useless without the human personality and the trained mind that can draw conclusions from the factors indicated. As simple a thing as an electric meter "registers exactly"—but how many people who pay electric bills can tell just what it registers or what it means. It's simply an aid to the electric company in making its diagnosis of the customer's liability, and a human mind is required to read the meter and calculate the liability. We say that we were examined or our case was diagnosed by or with an X-ray, or an electro-cardiograph or something else, and that the X-ray showed so and so or the electro-cardiograph reading showed such and such a condition, but we don't mean to intimate that anything was done without the intervention of a trained mind and no one would think of attributing any such meaning to our statement.

The Leaflets Did Not "Accompany" the Devices so as to Constitute "Labeling".

The present litigation began with the filing of a libel under the provisions of the Federal Food, Drug, and Cosmetic Act—specifically:

> Sec. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. * * *

Working backwards in an analysis of the situation we find that the devices were found within the jurisdiction of the District Court where the libel was filed AFTER they had been in interstate commerce and were in use in a doctor's office. So far so good—but were they "misbranded WHEN INTRODUCED INTO or WHILE IN INTERSTATE COMMERCE"?

> Sec. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

For the sake of argument we will assume that the leaflets contained false or misleading statements. But were the leaflets "labeling"?

> Sec. 201. For the purposes of this Act—* * * (m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The leaflets complained of were not "upon" the devices "or any of its containers or wrappers". Now did the leaflets "accompany" the devices? It might be said that the leaflets and the devices were accompanying each other

in the doctor's office in Ohio. Six of the leaflets were found in his suite of offices and the devices were also in his suite of offices. Two of the leaflets were on the doctor's desk and four in it. The devices were in other rooms (R. 20). They were accompanying each other just like two patients who came in at different times and were in different rooms. But that was AFTER the devices had passed out of interstate commerce, so we will say for the sake of argument that the devices were misbranded AFTER SHIPMENT IN INTERSTATE COMMERCE. Now that might have been a crime under

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
>
> * * * * * *
>
> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

if the devices were being held for sale (which they were not) but such a violation as that would not be a basis for a libel—and this was a libel and not a prosecution.

We back on up further and we find from the undisputed evidence of Petitioner's own witnesses that the devices and the leaflets were shipped at different times by different mediums of transportation, arrived at different times and were not even in interstate commerce simultaneously at any given moment. Now the leaflets could not be "labeling" except while "accompanying" the devices, and the devices would not be subject to libel unless misbranded "when introduced into or while in interstate commerce", so to sustain its libel Petitioner must show that the leaflets accompanied the devices "when (the devices) introduced into or while in interstate commerce". The evidence is absolutely to the contrary. Now that ought to end the matter and

require a dismissal of the libel—and that's what the Circuit Court of Appeals thought.

When confronted with the opinion of the Circuit Court of Appeals, however, the administrators of the Act just couldn't bear to have their wings clipped so they would have to stay within the bounds Congress prescribed for them. As a last resort they turned to spiritualism—went into a trance—and were finally able to see the ethereal forms of the devices and the leaflets floating on a cloud in the spirit world, accompanying each other in spirit—in a "textual relationship" if you please. All we need now is for the Interstate Commerce Commission to go into a trance and take jurisdiction over the spiritual means of transportation so we can call it interstate commerce.

The idea that the jurisdictional factor of printed matter "accompanying devices when introduced into or while in interstate commerce" is present when they were never even in interstate commerce at the same time, is utterly ridiculous.

Words are but the tools of men. Skilled artisans choose their tools carefully and use them rightly for the purpose they were made. The careless or ignorant often misuse a tool, dulling it and damaging that on which they use it. So it is with words. The Congress used perfectly clear and plain language in the statutory provisions under discussion in this case, and it requires the worst kind of distortion to eliminate physical contiguity from the necessary connotation of the word "accompanying," and to substitute therefor some spiritual relationship. If the Congress had intended for the libel provision of the statute to apply to shipments misbranded AFTER shipment in interstate commerce it would have said so—just as it provided Sec. 301(k) to make misbranding punishable if done while an article was held for sale after interstate shipment.

The Leaflets Were Not in Their Nature Labeling of the Devices.

The opinion of the Circuit Court of Appeals (R. 181, second paragraph) discusses the nature of the leaflet. The question is a very practical one—a question of fact to be determined by good common sense. The Circuit Court of Appeals has so approached it—and although it was not necessary for the Court to decide whether or not the leaflets were in their nature labeling—the Court expressed its serious doubt that they were.

The leaflets are an advertisement of an institution where personal and professional services are offered for sale in treatment of the sick and in training or teaching. The Sinuothermic device is mentioned as an instrumentality used in the institution but such mention is incidental to the advertisement of the services offered. Dr. Kelsch, Respondent's witness, testified that he got the leaflets to mail out to his patients and that he did so (R. 30). Respondent introduced in evidence a printed form letter on the letterhead of Sinuothermic Institute, Inc., and signed by Dr. Urbuteit, addressed to Dear Patient. This letter does not appear in the record but its identification and the statement that it was obtained from Dr. Kelsch appears (R. 19). The letter was mailed by Dr. Kelsch with the leaflets to his patients and is a message from Dr. Urbuteit to the patient stating that Dr. Kelsch has taken a course in Sinuothermic and is prepared to "carry on this advanced scientific work in his own office". There is no mention whatever of any kind of device or equipment. This letter illustrates the purpose and inherent nature of the leaflets and makes perfectly clear the fact that they are an advertisement of a professional service and not an advertisement of a device—much less a labeling of a device.

Conclusion.

The Circuit Court of Appeals wrote a sound and sensible opinion and supported it with logical reasoning. For the reasons stated in the opinion itself and the further reasons herein stated that opinion should stand and the judgment of the Circuit Court of Appeals should be affirmed.

Respectfully submitted,

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Attorney for Respondent.

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